Evaluation of Supplemental Nutrition in Elderly Orthopaedic Patients

A Thesis presented for the degree of Doctor of Philosophy
by
Lynn Driver B.Sc. (Hons)
March 1994

The Nutritional Metabolism Research Group School of Biological Sciences
University of Surrey
Guildford
Surrey
UK
"Only when the assessment of every patient's nutritional status has become a routine will the full benefits of nutritional treatment be realised."

*Kings Fund Centre Report (1992)*

"The achievement of a treatment goal is dependent upon accurate diagnosis, appropriate therapy and adequate compliance."

*Seltzer et al., (1980).*
ABSTRACT

A degree of malnutrition is evident in many elderly patients on admission to hospital. The increased metabolic demands of surgery, and low food intake during the post operative period, can cause a further deterioration in nutritional status, with adverse effects on clinical outcome. Sip feed supplements offer a simple and inexpensive method of providing nutrition support. The present study has evaluated the efficacy of, and compliance to, sip feed supplements in elderly patients undergoing elective and emergency orthopaedic surgery.

The feasibility study (Chapter 3) revealed that the patients who were not offered supplements throughout their hospital stay (NS group) demonstrated significant mean (± sd) losses in arm anthropometric measurements (-0.56 ± 2.9 mm in TSF, -1.15 ± 1.02 cm in MUAC and -1.04 ± 1.28 cm in MUAMC). No such losses were observed in the group receiving the supplements (S group). Compliance to the regimen was 61%.

In the long term evaluation study (Chapter 4) the period of supplementation was extended for a further four weeks into the discharge period, and patients were followed up for six months after discharge. Compared with the supplement (S) group, the non-supplemented (NS) patients showed adverse recovery, notably:

1) Significant losses in MUAC from admission to 8 weeks post discharge.

2) Longer duration of stay in hospital (total median hospital time in the NS group 33 days, compared with 22 in S group).

3) Higher rates of post-operative complications (six patients in the NS group developed chest infection, compared with one in the S...
group; 14 patients in the NS group developed pressure sores compared with 7 in the S group).

4) Higher rates of mortality in the period of study (20% in the NS group, compared with 9.5% in the S group).

Compliance was poor, at 62%. Intake of normal foods was not adversely affected by supplement intake. In an attempt to improve compliance, a nutrition education programme (NEP) was implemented (Chapter 5). The NEP did not significantly improve the rate of compliance. Further detailed food intake assessments confirmed that the provision of nutritional supplements did not reduce the intake of normal foods.

Sip feed supplements offer important measurable benefits to elderly patients recovering from orthopaedic surgery. Potential benefit was limited by poor patient acceptability. Compliance could not be improved by measures adopted in normal dietetic practice, nor by the implementation of a patient and nurse nutrition education programme.
Table Of Contents

Chapter 1
General Introduction

1.1 DEMOGRAPHY OF THE ELDERLY .............................. 1

1.2 THE PROCESS OF AGING ......................................... 3

1.2.1 Changes in organ systems ..................................... 3
1.2.1.1 Perceptual changes .................................. 3
1.2.1.2 Gastrointestinal changes ............................... 4
1.2.1.3 Endocrine changes ...................................... 4
1.2.1.4 Cardiovascular changes .................................. 4
1.2.1.5 Renal changes .......................................... 5
1.2.1.6 Immune function ....................................... 5
1.2.1.7 Neurological changes ................................ 5

1.2.2 Changes in body consumption ................................ 6
1.2.2.1 Lean body mass ........................................ 6
1.2.2.2 Body fat ................................................ 6
1.2.2.3 Total body water ....................................... 6
1.2.2.4 Bone mass .............................................. 7

1.2.3 Changes in metabolism ........................................ 7
1.2.3.1 Energy .................................................. 8

1.3 NUTRITION AND THE ELDERLY ................................. 9

1.3.1 The influence of nutrition on the process of ageing .......... 9

1.3.2 Body weight and mortality in the aged ..................... 10

1.3.3 Nutritional needs of the elderly ............................. 11
1.3.3.1 Energy ................................................ 11
1.3.3.2 Protein ............................................... 11
1.3.3.3 Vitamins and minerals ................................. 12

1.4 NUTRITIONAL SURVEYS OF THE ELDERLY .................... 13

1.5 CAUSES OF NUTRITIONAL PROBLEMS IN THE ELDERLY ......... 16

1.6 MALNUTRITION IN HOSPITAL ................................. 18


Chapter 2
Methods And Materials

2.1 INTRODUCTION .............................................. 46

2.2 REVIEW OF METHODS CURRENTLY AVAILABLE
FOR THE ASSESSMENT OF NUTRITIONAL
STATUS ........................................................ 47

2.2.1 Subjective clinical assessment ............................. 47

2.2.2 Anthropometric assessments .............................. 48
  2.2.2.1 Body weight ........................................ 49
  2.2.2.2 Skinfold thickness .................................. 50
  2.2.2.3 Mid Upper Arm Circumference (MUAC) .......... 52
  2.2.2.4 Mid Upper Arm Muscle Circumference
           (MUAMC) ........................................... 52

2.2.3 Body fat composition by underwater weighing .......... 53

2.2.4 Total body $^{40}$K ......................................... 54
2.2.5 Neutron activation .................................................. 55
2.2.6 Tritium or deuterium labelled water (H₂O) ..................... 55
2.2.7 Bio-electrical impedance ........................................... 55
2.2.8 Infra-red reactance ................................................ 56
2.2.9 Dual Energy X-ray absorptiometry ................................ 56
2.2.10 Computerise Tomography (CT) Scanning ....................... 56
2.2.11 Magnetic Resonance Imaging (MRI) ............................. 57
2.2.12 Biochemical assessments ......................................... 57
  2.2.12.1 Serum Albumin (ALB) ....................................... 57
  2.2.12.2 Serum Retinol Binding Protein (RBP) ...................... 58
2.2.13 Functional assessments ........................................... 58
  2.2.13.1 Hand grip strength .......................................... 58
  2.2.13.2 Mental function .............................................. 59
2.2.14 Nutrient intake data .............................................. 60
  2.2.14.1 Dietary surveys ............................................. 61
  2.2.14.2 24 hour dietary recall ...................................... 61
            2.2.14.3 Interview technique to establish "usual"
                  food intake ............................................... 61
  2.2.14.4 Weighed food intake ....................................... 62
  2.2.14.5 Diet records using household measures ................... 62
  2.2.14.6 Food frequency questionnaires ............................ 63
  2.2.14.7 Food Recording Electronic Device (FRED) ............... 63
  2.2.14.8 The use of food photographs ............................... 64
2.2.15 Combination indices ............................................. 64
2.3 SUMMARY ............................................................... 66
2.4 METHODS EMPLOYED .................................................. 68
  2.4.1 Nutrition Risk Questionnaire .................................. 68
  2.4.2 Anthropometric assessments .................................... 69
    2.4.2.1 Body weight ............................................... 69
    2.4.2.2 Triceps Skinfold Thickness (TSF) ......................... 70
    2.4.2.3 Mid Upper Arm Circumference (MUAC) ...................... 72
    2.4.2.4 Mid Upper Arm Muscle Circumference (MUAMC) ........... 72
Chapter 3
Feasibility Study

3.1 INTRODUCTION .............................................. 85

3.2 PATIENTS, PROCEDURES, ASSESSMENTS AND
EXPERIMENTAL DESIGN ........................................ 91
3.2.1 Patients ................................................... 91
3.2.2 Procedures ................................................. 91

3.3 ASSESSMENTS ................................................. 93
3.3.1 Anthropometric assessments .................................. 93
3.3.2 Biochemical assessments .................................. 93
3.3.3 Functional assessments ................................... 94
3.3.4 Clinical assessments ...................................... 94

3.4 OUTLINE OF EXPERIMENTAL DESIGN ...................... 96

3.5 STATISTICAL ANALYSIS AND PRESENTATION OF RESULTS ........................................ 97

3.6 RESULTS .......................................................... 98
3.6.1 Patient details ............................................... 98
3.6.2 Admission characteristics .................................. 98
3.6.3 Admission measurements .................................. 98
3.6.4 Changes in anthropometry and serum albumin from admission to discharge .................. 102
3.6.5 Indices of clinical outcome ................................ 105
3.6.6 Nutritional value of supplements consumed ........... 106

3.7 DISCUSSION ....................................................... 108

3.8 CONCLUSIONS AND FUTURE PLANNING ...................... 114
4.4.5.1 Serum albumin (ALB) ........................................... 167
4.4.5.2 Retinol Binding Protein (RBP) ............................ 171

4.4.6 Changes in voluntary Hand Grip Strength (vHGS) from admission to 6 months post-discharge .......... 174

4.4.7 Changes in mental function (CAPE score) from admission to 6 months post-discharge .................. 177

4.4.8 Clinical outcome data .............................................. 180
4.4.8.1 Duration of stay and place to which discharged from hospital ........................................... 180
4.4.8.2 Place of living and independence of mobility (modified VISICK score) at subsequent assessment periods following discharge from the acute hospital ........................................... 184
4.4.8.3 Complications .................................................... 190
4.4.8.4 Mortality .......................................................... 192

4.4.9 Nutrient intake data .................................................. 196
4.4.9.1 Nutritional intake from supplements ........................................... 196
4.4.9.2 Nutritional intake from normal foods (24 hour dietary recalls) ........................................... 199
4.4.9.3 Nutritional intake from normal foods and nutritional supplement ........................................... 204
4.4.9.4 Comparisons of protein and energy intakes with the Department of Health (1991) current recommendations ........................................... 207

4.5 DISCUSSION ............................................................. 211
4.5.1 Recruitment and compliance rates ........................................... 214
4.5.2 Admission characteristics and baseline measurements ........................................... 218
4.5.3 Changes in anthropometric and biochemical indices over the period of study ........................................... 227
4.5.4 Changes in functional indices over the period of study ........................................... 233
4.5.5 Clinical outcome ...................................................... 236
4.5.6 Dietary intakes ......................................................... 249
4.5.6.1 Nutritional intakes from supplements ........................................... 249
4.5.6.2 Nutritional intakes from normal foods (24 hour recalls) ........................................... 250
Chapter 5
The Effect Of A Nutrient Education Programme
On Patient Compliance To Sip Feed
Supplements And Further Investigations
Regarding The Effect Of Supplement
Consumption On Nutritional Intake From
Normal Foods

5.1 INTRODUCTION ........................................... 263
  5.1.1 Acceptability of nutritional supplements .............. 266
  5.1.2 Compliance to medical regimens ..................... 267
  5.1.3 Compliance to dietary regimens .................... 268
  5.1.4 Factors which influence compliance ................ 269
      5.1.4.1 The influence of attitudes and benefits ...... 271
      5.1.4.2 Knowledge and the effect of nutrition
             education on compliance .................. 274

5.2 AIMS OF THE STUDY ...................................... 279

5.3 SUBJECTS AND METHODS ................................ 280
  5.3.1 Patients ............................................ 280
  5.3.2 Experimental design ............................... 281
      5.3.2.1 "Nutrition and Illness" Questionnaire ....... 283
      5.3.2.2 Anthropometric assessments ................ 283
      5.3.2.3 Clinical assessments ........................ 284
      5.3.2.4 Nutritional and dietary assessments ....... 284
      5.3.2.5 The nutritional supplement ................. 285
      5.3.2.6 Nutrition Education Programme (NEP) ....... 285
5.3.2.6.1 Nutrition Education Programme (NEP) for ward staff ........................... 285
5.3.2.6.2 Nutrition Education Programme (NEP) for patients .......................... 287

5.4 STATISTICAL ANALYSIS AND PRESENTATION OF RESULTS ......................................................... 289

5.5 RESULTS ............................................................................................................................................. 290

5.5.1 Recruitment of patients and admission characteristics .............................................. 290

5.5.2 The effect of the Nutrition Education Programme (NEP) on compliance to the supplement (Fortisip) ................................. 291

5.5.3 Compliance in relation to age, type of admission and response to the NRQ ......................... 293

5.5.4 Results of the "Nutrition and illness" questionnaire ................................................. 295

5.5.5 Reasons given by patient for non-compliance .......................................................... 298

5.5.6 Total volume of supplement consumed .................................................................. 298

5.5.7 Nutritional intakes of compliant (C) compared with non-compliant (NC) patients ................................................... 298

5.5.8 Nutritional intakes of the group of patients who received the Nutrition Education Programme (NEP) compare with the group who were not offered the NEP .................................................................................. 302

5.5.9 Body weight, anthropometry and hand grip strength (baseline values and changes from admission to discharge) ............................................. 304

5.5.10 Duration of stay in hospital (admission to discharge) ........................................... 304

5.6 DISCUSSION ....................................................................................................................................... 307

5.6.1 The effect of the Nutrition Education Programme (NEP) on patient compliance to sip feed supplements ......................................................... 307

5.6.2 Factors associate with poor compliance ................................................................. 312
5.6.3 The use of alternative supplements to increase nutrient intake ........................................ 315
5.6.4 The effect of the ingestion of supplements on the nutritional intake from normal foods .......... 316
5.6.5 Outcome of compliant and non-compliant patients ........ 319
5.7 CONCLUSION ......................................................... 320

Chapter 6
General Discussion

6.1 GENERAL DISCUSSION ......................................................... 322
6.2 RECOMMENDATIONS FOR FUTURE WORK .................. 336

References

Appendices

APPENDIX I

Table A1.1 The elderly female population in the UK (mid year population in thousands) .......... i
Table A1.2 The elderly male population in the UK (mid year population in thousands) .......... i

APPENDIX II

Nutrition Risk Questionnaire ........................................ ii
Northwick Park Mental Function Memory and Awareness Test ........................................ iv
Cognitive Assessment Procedures for the Elderly (CAPE) Cognitive Assessment Scale (CAS) .......... v
Reading list for CAPE CAS ................................................ vi
Instructions and scoring for CAS ....................................... vii
APPENDIX III

Table A3.1 Nutritional composition of Ensure .............. viii
Details of patients recruited into the feasibility study ................................................. ix

APPENDIX IV

Table A4.1 Nutritional composition of supplements offered to patients in the long term follow up study ......................... x
Details of patients recruited into the long term follow up study .................................................. xi

Table A4.2 Volume of supplements consumed by individual patients in the S-NS sub-group and the reason given for not wishing to continue with the regimen ......................... xii

Table A4.3.i Daily protein and energy intakes from normal foods (24 hr dietary recalls) of the individual patients in the S-C sub-group ........................................ xiii

Table A4.3.ii Daily protein and energy intakes from normal foods (24 hr dietary recalls) of the individual patients in the S-NC sub-group ................................. xiv

Table A4.3.iii Daily protein and energy intakes from normal foods (24 hr dietary recalls) of the individual patients in the NS-CP sub-group ................................. xv

Table A4.3.iv Daily protein and energy intakes from normal foods (24 hr dietary recalls) of the individual patients in the NS-NCP sub-group ................................. xvi

APPENDIX V

Table A5.1 Nutritional composition of fortisip ..................... xvii
Details of patients recruited into the NEP study ................. xviii

Nutrition and Illness Questionnaire ......................... xix

Handouts for nurses to support nutrition education lectures ......................................................... xxi

Table A5.2 Individual patient scores for the Nutrition and Illness Questionnaire ........ xxxiv

Table A5.3 Nutritional intakes of compliant (including and excluding the supplement) and the non-compliant groups, expressed for the three individual days of assessment and as the mean of the three days .................. xxxv

Table A5.4 Nutritional intakes of the group receiving the NEP (excluding the supplement) and the group who were not offered the NEP, expressed for three individual days of assessment as well as the mean of the three days .......... xxxvi
List Of Figures

Chapter 1

1.1 The elderly and total female population in the UK 1961-1990 (mid year population) ......................... 2
1.2 The elderly and total male population in the UK 1961-1990 (mid year population) ............................... 2

Chapter 3

3.1 Recruitment and categorisation of patients into the feasibility study .................................................. 96

Chapter 4

4.1 Number of male and female patients admitted to the accident and emergency department of the RSCH with a fractured femur between June 1986 and May 1987 ..................................................... 130
4.2 Recruitment categorisation of patients into the long term follow up study ............................................. 142
4.3 Distribution of NRS for the seventy three patients interviewed ............................................................... 147
4.4a Body weight measurements (Kg) observed in the S and NS groups from hospital to six months post-discharge .............................................................. 156
4.4b Body weight measurements (Kg) observed in the S-C and NS-CP sub groups from hospital to six months post-discharge ...................................................... 157
4.5a Triceps skinfold thickness measurements (TSF) (mm) observed in the S and NS groups from hospital to six months post-discharge ........................................... 159
4.5b Triceps skinfold thickness measurements (TSF) (mm) observed in the S-C and NS-CP
4.6a Mid upper arm circumference measurements (MUAC) (cm) observed in the S and NS groups from hospital to six months post-discharge .............................................. 160

4.6b Mid upper arm circumference measurements (MUAC) (cm) observed in the S-C and NS-CP sub-groups from hospital to six months post-discharge .............................................. 162

4.7a Mid upper arm muscle circumference measurements (MUAMC) (cm) observed in the S and NS groups from hospital to six months post-discharge .............................................. 163

4.7b Mid upper arm muscle circumference measurements (MUAMC) (cm) observed in the S-C and NS-CP sub-groups from hospital to six months post-discharge .............................................. 165

4.8a Serum albumin (g/dl) measurements observed in the S and NS groups from hospital to six months post-discharge .............................................. 166

4.8b Serum albumin (g/dl) measurements observed in the S-C and NS-CP sub-groups from hospital to six months post-discharge .............................................. 168

4.9a Serum retinol binding protein measurements (RBP) (mg/l) observed in the S and NS groups from hospital to six months post-discharge .............................................. 169

4.9b Serum retinol binding protein measurements (RBP) (mg/l) observed in the S-C and NS-CP sub-groups from hospital to six months post-discharge .............................................. 170

4.10a Voluntary hand grip strength measurements (vHGS) (lb/in²) observed in the S and NS groups from hospital to six months post-discharge .............................................. 171

4.10b Voluntary hand grip strength measurements (vHGS) (lb/in²) observed in the S-C and NS-CP sub-groups from hospital to six months post-discharge .............................................. 172

...
4.11a Mental function test score (MFT) (%) in the S and NS groups from hospital to six months post-discharge .......................................................... 178

4.11b Mental function test score (MFT) (%) observed in the S-C and NS-CP sub groups from hospital to six months post-discharge ........................................ 179

4.12a Duration of stay in hospital (acute, convalescence and total) experienced by the S and NS groups .......................................................... 182

4.12b Duration of stay in hospital (acute, convalescence and total) experienced by the S-C and NS-CP sub groups ........................................... 183

4.13a VISICK SCORE in the S and NS groups from 1 week to six months post-discharge .......................................................... 187

4.13b VISICK SCORE in the S-C and NS-CP sub groups from 1 week to six months post-discharge ....................................................... 188

4.14a Daily protein intakes of the S and NS groups from normal foods (excluding the nutritional supplement), calculated from 24 hour dietary recall .......................................................... 201

4.14b Daily protein intakes of the S-C and NS-CP sub groups from normal foods (excluding the nutritional supplement), calculated from 24 hour dietary recall .......................................................... 202

4.14c Daily protein intakes of the S-C and S-NC groups from normal foods (excluding the nutritional supplement), calculated from 24 hour dietary recall .......................................................... 203

4.15a Daily energy intakes of the S and NS groups from normal foods (excluding the nutritional supplement), calculated from 24 hour dietary recall .......................................................... 201

4.15b Daily energy intakes of the S-C and NS-CP sub groups from normal foods (excluding the nutritional supplement), calculated from 24 hour dietary recall .......................................................... 202
4.15c Daily energy intakes of the S-C and S-NC sub-groups from normal foods (excluding the nutritional supplement), calculated from 24 hour dietary recall ................................. 203

4.16 Total daily protein intakes of the four sub groups; S-C (including nutritional supplement), NS-CP, S-NC, and NS-CP ........................................ 205

4.17 Total daily energy intakes of the four sub groups; S-C (including nutritional supplement), NS-CP, S-NC, and NS-CP ........................................ 206

Chapter 5

5.1 Recruitment and categorisation of patients into the Nutrition Education Programme ..................... 282

5.2 Intakes of energy, protein, fat and carbohydrate (mean 3 days) for the compliant (C) and non-compliant (NC) groups in hospital ..................... 299

5.3 Normal dietary intake (as assessed by and initial diet history) expressed for the Compliant (C) and Non-Compliant (NC) sub-groups .................... 301

5.4 Intakes of energy, protein, fat and carbohydrate (mean of 3 days) for the group who received the NEP and the group who were not offered the NEP (N-NEP) ........................................ 303

5.5 Normal dietary intake (as assessed by and initial diet history) expressed for the group receiving the NEP and the group not offered the NEP (N-NEP) ........................................ 305
List Of Tables

Chapter 3

3.1 Feasibility study, summary of assessment procedures ................................................. 95
3.2 Summary of the admission characteristics of HR (S) and HR (NS) groups ......................... 99
3.3 Admission measurements of the High Risk supplement and the High Risk non-supplement groups ....................................... 100
3.4 Summary of the changes in anthropometric measurements from admission to discharge in the HR-Supplement and the HR-Non-Supplement groups ................................. 102
3.5 Summary of the changes in the anthropometric measurements from admission to discharge in the HR-Supplement (Compliant & Non-Compliant) and the HR-Non-Supplement (Admission pairs to Compliant & Non-Compliant) groups ......................... 104
3.6 Summary of clinical outcome in the Supplement and Non-Supplement groups ....................... 106

Chapter 4

4.1 A summary of procedures and assessments ........................................... 134
4.2 A summary of admission characteristics (age, type of admission and NRS) of the total group of patients interviewed expressed as the total group the LR and HR categories and the HR-S and HR-NS groups ........................................... 145
4.3 Summary of admission characteristics (age, type of admission and NRS) of the four subgroups: S-C, NS-CP, S-NC and NS-NCP ........................................... 146
4.4 Results of routine hospital blood tests (creatinine, haemoglobin, white cell count) on admission, for the S and NS groups, and the S-C and NS-CP sub-groups .................. 149

4.5 Baseline measurements for the S and NS groups, and the S-C and NS-CP sub-groups ............................................. 150

4.6 Comparison between baseline measurements for the S and NS groups, for the patients in the feasibility and long term studies .................. 152

4.7a Body weight measurements (Kg) observed in the S and NS groups from hospital to six months post-discharge .............................................. 156

4.7b Body weight measurements (Kg) observed in the S-C and NS-CP sub groups from hospital to six months post-discharge .............................................. 157

4.8a Triceps skinfold thickness measurements (TSF) (mm) observed in the S and NS groups from hospital to six months post-discharge .............................................. 159

4.8b Triceps skinfold thickness measurements (TSF) (mm) observed in the S-C and NS-CP sub groups from hospital to six months post-discharge .............................................. 160

4.9a Mid upper arm circumference measurements (MUAC) (cm) observed in the S and NS groups from hospital to six months post-discharge .............................................. 162

4.9b Mid upper arm circumference measurements (MUAC) (cm) observed in the S-C and NS-CP sub groups from hospital to six months post-discharge .............................................. 163

4.10a Mid upper arm muscle circumference measurements (MUAMC) (cm) observed in the S and NS groups from hospital to six months post-discharge .............................................. 165

4.10b Mid upper arm muscle circumference measurements (MUAMC) (cm) observed in the S-C and NS-CP sub groups from hospital to six months post-discharge .............................................. 166
4.11a Serum albumin (g/dl) measurements observed in the S and NS groups from hospital to six months post-discharge ...................... 169

4.11b Serum albumin (g/dl) measurements observed in the S-C and NS-CP sub groups from hospital to six months post-discharge ...................... 170

4.12a Serum retinol binding protein measurements (RBP) (mg/l) observed in the S and NS groups from hospital to six months post-discharge ...................... 172

4.12b Serum retinol binding protein measurements (RBP) (mg/l) observed in the S-C and NS-CP sub groups from hospital to six months post-discharge ...................... 173

4.13a Voluntary hand grip strength measurements (vHGS) (lb/in²) observed in the S and NS groups from hospital to six months post-discharge ...................... 175

4.13b Voluntary hand grip strength measurements (vHGS) (lb/in²) observed in the S-C and NS-CP sub groups from hospital to six months post-discharge ...................... 176

4.14a Mental function test score (MFT) (%) in the S and NS groups from hospital to six months post-discharge ...................... 178

4.14b Mental function test score (MFT) (%) observed in the S-C and NS-CP sub groups from hospital to six months post-discharge ...................... 179

4.15a Duration of stay in hospital (acute, convalescence and total) experienced by the S and NS groups ..................... 182

4.15b Duration of stay in hospital (acute, convalescence and total) experienced by the S-C and NS-CP sub groups ..................... 183

4.16a Place of living at the time periods of assessment following discharge from the acute hospital, for the S and NS groups ..................... 185
4.16b Place of living at the time periods of assessment following discharge from the acute hospital, for the S-C and NS-CP sub-groups ............................. 186

4.17a VISICK SCORE in the S and NS groups from 1 week to six months post-discharge ........................................ 187

4.17b VISICK SCORE in the S-C and NS-CP groups from 1 week to six months post-discharge ................................. 188

4.18 Number of patients experiencing complications during the period of study, in the S and NS groups and the S-C and NS-CP sub-groups ........................................ 191

4.19 Mortality rates of the S and NS groups and the S-C and NS-CP sub-groups at each of the periods of assessment ............................................. 193

4.20 Admission characteristics and baseline values of the patients who died during the period of study ................. 195

4.21 Median daily intake of nutritional supplements consumed by each patient in the S-C sub-group, whilst in the acute hospital ........................................ 197

4.22 Median daily intake of nutritional supplements consumed by each patient in the S-C sub-group, during the four weeks following discharge from the acute hospital ............................. 198

4.23a Daily protein intakes of the S and NS groups from normal foods (excluding the nutritional supplement), calculated from 24 hour dietary recall ........................................... 201

4.23b Daily protein intakes of the S-C and NS-CP sub groups from normal foods (excluding the nutritional supplement), calculated from 24 hour dietary recall ..................................... 202

4.23c Daily protein intakes of the S-C and S-NR sub groups from normal foods (excluding the nutritional supplement), calculated from 24 hour dietary recall ..................................... 203

4.24a Daily energy intakes of the S and NS groups from normal foods (excluding the nutritional supplement), calculated from 24 hour dietary recall ........................................... 204
supplement), calculated from 24 hour dietary recall ..................................................... 201

4.24b Daily energy intakes of the S-C and NS-CP sub groups from normal foods (excluding the nutritional supplement), calculated from 24 hour dietary recall ..................................................... 202

4.24c Daily energy intakes of the S-C and S-NC sub groups from normal foods (excluding the nutritional supplement), calculated from 24 hour dietary recall ..................................................... 203

4.25 Total daily protein intakes of the four sub groups; S-C (including nutritional supplement), NS-CP, S-NC, and NS-CP ..................................................... 205

4.26 Total daily energy intakes of the four sub groups; S-C (including nutritional supplement), NS-CP, S-NC, and NS-CP ..................................................... 206

4.27 Department of Health (1991) dietary reference values for protein and energy intakes in the UK elderly female population ..................................................... 209

4.28 Number (%) of patients whose daily intake of protein from normal foods (calculated from 24 hour dietary recall) was less that Department of Health (1991) recommendations ..................................................... 210

4.29 Number (%) of patients whose daily intake of energy from normal foods (calculated from 24 hour dietary recall) was less than the Department of Health (1991) recommendations ..................................................... 210

4.30 Number (%) of patients whose total daily intake of protein and energy (normal foods and supplement) was less than the Department of Health (1991) recommendations ..................................................... 210

Chapter 5

5.1 Summary of admission characteristics (age, type of admission and NRS) expressed as the total group of patients, and sub-divided into
the group who received the NEP and those who were not offered the NEP ........................................ 291

5.2 Comparison of compliance rates between those patients receiving the Nutrition Education Programme (NEP) and those who were not offered it ........................................ 292

5.3 Summary of admission characteristics (age, type of admission and NRS) expressed as the total group of patients studied, and sub-divided into the Compliant and Non-Compliant sub-groups ........................................ 293

5.4 Comparison of mean NRS and some responses to the NRQ between the compliant and non-compliant groups ........................................ 295

5.5 Comparison of scores obtained from the "Nutrition and Illness" questionnaire ........................................ 297

5.6 Intakes of energy, protein, fat and carbohydrate (mean of 3 days) for the compliant (C) and non-compliant (NC) groups in hospital ........................................ 299

5.7 Normal dietary intake (as assessed by an initial diet history) expressed for the Compliant (C) and Non-Compliant (NC) sub groups ........................................ 301

5.8 Intakes of energy, protein, fat and carbohydrate (mean of 3 days) for the group who received the NEP and the group who were not offered the NEP (N-NEP) ........................................ 303

5.9 Normal dietary intake (as assessed by and initial diet history) expressed for the group receiving the NEP and the group not offered the NEP (N-NEP) ........................................ 305

5.10 Body weight, anthropometry (MUAC, TSF), hand grip strength and percentage body fat of the compliant (C) and non-compliant (NC) groups ........................................ 306
Acknowledgements

There are many people who have provided me with support and encouragement during the writing of this thesis and to whom I would like to express my deepest gratitude.

Firstly, to my supervisor Dr Christine Williams for her support, guidance and understanding throughout the past few years. I am grateful to Maggie Lumbers, to Janet Bisson and Francis Blades who assisted in the running of this study and helped out in times of need. I would also like to thank Abbot Laboratories and Cow and Gate for the provision of the sip feed supplements and financial support, and the South West Thames Regional Health Authority for funding the initial study.

I am indebted to Orthopaedic Consultants of the Royal Surrey County Hospital, particularly to Mr John Older for his encouragement and enthusiasm, and to the medical staff of Bramshott and Ewhurst Ward for their cooperation and assistance. I would also like to thank the patients who have taken part in the studies, without whom the study would not have been possible.

I cannot forget my colleagues in the laboratory and a special thank you to Matthew for his assistance with the albumin and RBP assays.

More recently, I would like to thank all of the people with whom I now work for their continual encouragement and motivation. My special thanks must go to Sally, not only for her assistance with the typing and for proof reading this thesis, but for her tremendous support during the final stages.

Finally I would like to thank David, my husband, for his love and constant support which has enabled me to keep my motivation throughout the difficult times. He has sat beside me for many an hour producing the graphs and tables presented in this thesis, for which I am extremely grateful. With him beside me, I look forward to the future.
To David and my parents.
**LIST OF ABBREVIATIONS**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alb</td>
<td>Albumin</td>
</tr>
<tr>
<td>BCG</td>
<td>Bromo Cresol Green</td>
</tr>
<tr>
<td>BMR</td>
<td>Basal metabolic rate</td>
</tr>
<tr>
<td>bw</td>
<td>Body weight</td>
</tr>
<tr>
<td>C-ES</td>
<td>Compliant patients - nutritional intake excluding supplement</td>
</tr>
<tr>
<td>C-S</td>
<td>Compliant patients - nutritional intake including supplement</td>
</tr>
<tr>
<td>CAPE</td>
<td>Cognitive Assessment Procedures for the Elderly</td>
</tr>
<tr>
<td>CAS</td>
<td>Cognitive Assessment Scale</td>
</tr>
<tr>
<td>cm</td>
<td>Centimetres</td>
</tr>
<tr>
<td>dl</td>
<td>Decilitre</td>
</tr>
<tr>
<td>DRG</td>
<td>Diagnostic Retained Groups</td>
</tr>
<tr>
<td>EAR</td>
<td>Estimated Average Requirement</td>
</tr>
<tr>
<td>EEG</td>
<td>Electroencephalograph</td>
</tr>
<tr>
<td>FFM</td>
<td>Fat Free Mass</td>
</tr>
<tr>
<td>FNF</td>
<td>Fractured Neck of Femur</td>
</tr>
<tr>
<td>FRED</td>
<td>Food Recording Electronic Device</td>
</tr>
<tr>
<td>g</td>
<td>Grammes</td>
</tr>
<tr>
<td>GFR</td>
<td>Glomerular Filtration Rate</td>
</tr>
<tr>
<td>GH</td>
<td>Growth hormone (somatonorm)</td>
</tr>
<tr>
<td>GRU</td>
<td>Geriatric Rehabilitation Unit</td>
</tr>
<tr>
<td>HR</td>
<td>High Risk</td>
</tr>
<tr>
<td>IGF</td>
<td>Insulin-like growth factor</td>
</tr>
<tr>
<td>IVF</td>
<td>Intravenous Fluids</td>
</tr>
<tr>
<td>IVN</td>
<td>Intravenous nutrition</td>
</tr>
<tr>
<td>kcal</td>
<td>Kilocalories</td>
</tr>
<tr>
<td>kg</td>
<td>Kilogrammes</td>
</tr>
<tr>
<td>l</td>
<td>Litre</td>
</tr>
<tr>
<td>lb</td>
<td>Pound (imperial weight)</td>
</tr>
<tr>
<td>lb/in²</td>
<td>Pounds per square inch</td>
</tr>
<tr>
<td>LBM</td>
<td>Lean Body Mass</td>
</tr>
<tr>
<td>LR</td>
<td>Low Risk</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
</tr>
<tr>
<td>--------------</td>
<td>-------------</td>
</tr>
<tr>
<td>MFT</td>
<td>Mental Function Test</td>
</tr>
<tr>
<td>mg</td>
<td>Milligrammes</td>
</tr>
<tr>
<td>mm</td>
<td>Millimetres</td>
</tr>
<tr>
<td>mmHg</td>
<td>mm mercury</td>
</tr>
<tr>
<td>mmol</td>
<td>Millimoles</td>
</tr>
<tr>
<td>MUAC</td>
<td>Mid Upper Arm Circumference</td>
</tr>
<tr>
<td>MUAMC</td>
<td>Mid Upper Arm Muscle Circumference</td>
</tr>
<tr>
<td>N</td>
<td>Nitrogen</td>
</tr>
<tr>
<td>N-NEP</td>
<td>Group not offered the Nutrition Education Programme</td>
</tr>
<tr>
<td>NaCl</td>
<td>Sodium Chloride</td>
</tr>
<tr>
<td>NaOH</td>
<td>Sodium Hydroxide</td>
</tr>
<tr>
<td>NEP</td>
<td>Group receiving the Nutrition Education Programme</td>
</tr>
<tr>
<td>nm</td>
<td>Nano metres (wavelength of light)</td>
</tr>
<tr>
<td>NRQ</td>
<td>Nutrition Risk Questionnaire</td>
</tr>
<tr>
<td>NRS</td>
<td>Nutrition Risk Score</td>
</tr>
<tr>
<td>NS</td>
<td>Non Supplement group</td>
</tr>
<tr>
<td>NS-CP</td>
<td>Non Supplement Compliant &quot;admission Pairs&quot; sub group</td>
</tr>
<tr>
<td>NS-NCP</td>
<td>Non Supplement Non-Compliant &quot;admission Pairs&quot; sub-group</td>
</tr>
<tr>
<td>PCM</td>
<td>Protein Calorie malnutrition</td>
</tr>
<tr>
<td>PNI</td>
<td>Prognostic Nutritional Index</td>
</tr>
<tr>
<td>RBP</td>
<td>Retinol Binding Protein</td>
</tr>
<tr>
<td>RNI</td>
<td>Recommended Nutrient Intake</td>
</tr>
<tr>
<td>rpm</td>
<td>Revolutions per minute</td>
</tr>
<tr>
<td>RSCH</td>
<td>Royal Surrey County Hospital</td>
</tr>
<tr>
<td>S</td>
<td>Supplement group</td>
</tr>
<tr>
<td>S-C</td>
<td>Supplement Compliant sub-group</td>
</tr>
<tr>
<td>S-NC</td>
<td>Supplement Non-Compliant sub-group</td>
</tr>
<tr>
<td>sd</td>
<td>Standard deviation</td>
</tr>
<tr>
<td>SE</td>
<td>Standard Error</td>
</tr>
<tr>
<td>St</td>
<td>Stones (imperial weight)</td>
</tr>
<tr>
<td>TBM</td>
<td>Total Body Mass</td>
</tr>
<tr>
<td>THR</td>
<td>Total Hip Replacement</td>
</tr>
<tr>
<td>TPN</td>
<td>Total parental nutrition</td>
</tr>
</tbody>
</table>
TSF Triceps skinfold thickness
UTI Urinary Tract Infection
vHGS Voluntary Hand Grip Strength
WCC White Cell Count
yr Year
Chapter 1

General Introduction
Chapter 1
GENERAL INTRODUCTION

1.1 DEMOGRAPHY OF THE ELDERLY

Advances in medical care and control of disease have led to an increase in the proportion of the population surviving into old age. Currently there are approximately 10.5 million people of pensionable age in the UK, representing 18.3% of the population (OPCS, 1991). Over the next 20 years an increase is expected in the total number of people classified as elderly. The most dramatic increase is anticipated in the very elderly. The number of people over 85 years is projected to increase by about two thirds over this period (Government Actuary Dept, 1989). The number of individuals reaching ages in excess of 85 years is also increasing dramatically in both total number and proportion of the population, particularly females (Figures 1.1 and 1.2; numerical data can be found in Appendix I, Tables A1.1 to A1.2). In the UK the current average life expectancy is approximately 72 years for men and 78 years for women (OPCS, 1991). The term "elderly" is usually applied to individuals of pensionable age, although this term can cover an extremely heterogenous group of individuals with very different abilities and states of health. Of those who reach retirement, many enjoy a good, healthy and active life; indeed some very elderly people may maintain their enjoyment of full life beyond the life expectancy of an average person. However it should be remembered that there are a number of factors which influence both length and quality of life during this period.
Figure 1.1  The elderly and total female population in the UK 1961 - 1990 (mid year population). Source OPCS (1991)

Figure 1.2  The elderly and total male population in the UK 1961 - 1990 (mid year population). Source OPCS (1991)
1.2 **THE PROCESS OF AGEING**

The chronological age of 65 years has been selected to define the age of retirement and thereby can be regarded as signifying the beginning of "old age". However, the rate of ageing differs with each individual, and persons of the same chronological age can differ dramatically in terms of function and capability. Ageing is a multi-faceted event which encompasses molecular, cellular, physiological and psychological changes. The impact of these changes on the individual, coupled with the influence of external or environmental factors, determines the actual perception of ageing. Over the age of 30, normal physiological processes decline at a near-linear rate. Structural and functional changes occur at all levels from cells to organ systems, and at varying rates in different individuals. The extent to which these changes are regarded as purely physiological and to what extent their progression, or even onset, may be influenced by environmental and nutritional factors is uncertain.

The changes which occur during the ageing process fall into three main categories; changes in organ systems, in body composition and in metabolism.

1.2.1 **Changes in organ systems**
1.2.1.1 **Perceptual changes**

The senses of sight, hearing, taste and smell are all important factors associated with the enjoyment of eating and are frequently impaired in the elderly (Bidlack and Hamilton Smith, 1988). Additionally, a variety of medications and disease states can alter taste perception. Most elderly people of today have lost many of their natural teeth, thus mastication may be hindered by loose or missing teeth, periodontal disease, ill-fitting dentures or an altered biting surface. In the attempt to alleviate pain or embarrassment associated with eating, the aged individual frequently modifies food choices by making often inappropriate substitutions in the
diet, which may inadvertently affect nutritional intake and possibly lead to gastrointestinal disturbances.

1.2.1.2 Gastrointestinal changes
One of the most common complaints of the elderly is constipation. Several factors, including low fluid intakes, diets low in fibre, medications, physical inactivity, altered gastrointestinal motility and habitual inattention to respond to the defecation reflex, may contribute to poor bowel function. Regular use of laxatives to combat constipation can lead to a functional dependency and may cause malabsorption of some nutrients.

Other gastrointestinal changes associated with normal ageing include diminished gastric secretion of hydrochloric acid, pepsin, intrinsic factor and mucus, decreased pancreatic secretion and gall bladder abnormalities. All of these changes can reduce effective nutrient absorption and may cause the individual to avoid certain food groups for fear of “indigestion”.

1.2.1.3 Endocrine changes
The secretory function of endocrine glands and the activity of the hypothalamic pituitary axis decrease with ageing and there is a decreased tissue response to certain hormones. The net effect of these changes is a blunting of the homeostatic responses within the endocrine system.

1.2.1.4 Cardiovascular changes
Increased blood pressure, cardiac hypertrophy, decreased myocardial contractility and decreased cardiac output are some of the important changes that occur in the structure and function of the cardiovascular system which accompany the process of ageing. The resultant reduction in the delivery of oxygen to the tissues is partly responsible for the characteristic decline in capacity for exercise in older people. Management of such changes often involves treatment with drugs and dietary
restrictions, all of which can influence the nutritional status of the individual.

1.2.1.5 Renal changes
It is well recognised that various aspects of renal function decline with age (Rudman and Cohan, 1990). The kidney atrophies so the resultant renal mass at the age of 80 years is 30% less than at the age of 30 years. On average, renal blood flow and glomerular filtration rate (GFR) are diminished by approximately 50% from age 30 years to age 80 years. Structural and functional changes of the kidney include a loss in the number of nephrons (although those remaining may be enlarged), a reduced ability to concentrate urine and a diminished capacity to conserve sodium. Although the kidney has a remarkable capacity to lose a great percentage of its function before becoming incapable of maintaining homeostasis, the aged kidney may be inefficient in the removal of the waste products of protein metabolism, and may contribute to an increased blood urea nitrogen in the elderly. These biochemical abnormalities can create a feeling of nausea and anorexia.

1.2.1.6 Immune function
There is considerable evidence to support the existence of impaired immune function with increasing age, in both the animal model and in man. All cell types of the immune system seem to be subject to age related changes, but the thymus-derived lymphocytes (T-cells) seem to be the most affected (Chandra, 1990). There is a reduction in the circulating levels of serum Ig G and an increase in serum Ig A and auto-antibody levels.

1.2.1.7 Neurological changes
Altered brain activity patterns occur with ageing, as demonstrated by an increase in slow wave activity, slowing of alpha wave activity and an increase of beta wave activity in electroencephalograms (EEG’s) taken from older people (Tucker et al., 1990).
1.2.2 Changes in body composition
As people age, changes in body shape and appearance become apparent, many of which are associated with changes in composition.

1.2.2.1 Lean body mass
During adult life there is a gradual decrease in lean body mass (LBM). There is a decline in total body potassium which is generally interpreted to indicate a reduction in total protein mass. Cohn et al., (1980) have demonstrated that the age related decline in potassium is greater than that of nitrogen, suggesting that non-muscle protein mass is not affected by age, but that skeletal muscle mass is considerably reduced. The LBM of men peaks in their mid thirties and thereafter declines, but women maintain their LBM up until the age of about 50 years, after which it does decline but at a slower rate than men. Studies have shown that at 70 years, skeletal muscle has lost approximately 40% of its peak weight in adult life (Steen, 1988).

1.2.2.2 Body fat
Accompanying the decrease in LBM is an increase in body fat. This component rises slowly between the ages of 25 and 45 years, but continues to accumulate until the age of about 70-75 years, after which there is generally no further increase. Throughout life, women have a higher percentage of body fat than men, but the magnitude of increase in body fat with age is greater in men.

There is also a marked redistribution of body fat during ageing (Shimokata et al., 1989), with accumulation in the abdominal region, with a slight redistribution from subcutaneous sites to surrounding internal organs.

1.2.2.3 Total body water
Total body water decreases with advancing age. In men, this begins in middle age and continues throughout the remaining life span; in women
there is a less marked reduction at middle age, but a rapid decrease after the age of 60 years. Whether the decrease is due to extra-cellular or intra-cellular changes, or both, is not clear.

1.2.2.4 Bone mass
From the age of about 30 years, the bone mineral and matrix are removed more rapidly than the rate at which new bone is deposited. The "peak bone mass" is the major determinant of the bone mineral density present in later life. Beyond the third decade, there is a slow loss of bone over the next 20 years, at a rate of between 0.3 and 1.0%. In postmenopausal women, this loss is accelerated to between 3 and 5%. Trabecula bone is lost earlier than cortical bone. This reduction in bone mass, as well as causing the characteristic change in spinal shape in the elderly, also means that their long bones are more vulnerable to fracture.

1.2.3 Changes in metabolism
The effect of ageing on protein and amino acid metabolism has been reviewed by Munro (1981) and more recently by Young (1990a). As the reduction in skeletal mass occurs, there is a change in the pattern of protein synthesis and breakdown. If expressed per kg body weight, both protein synthesis and protein breakdown are lower in old people of both sexes compared with younger people, not surprising since older people have less muscle mass. When expressed in relation to creatinine excretion, rates of synthesis and breakdown are higher in elderly compared with young subjects (Munro, 1981; Young, 1990a, 1990b). Muscle accounts for approximately 30% of whole body protein turnover in young men compared with about 20% in elderly men.

It seems that elderly people are able to maintain an adequate metabolic capacity to respond to the needs of provision of amino acids. The influence of insulin on amino acid metabolism is similar in both young and old people, despite the recognised decline in insulin-mediated glucose uptake with age.
However, there is evidence to suggest that the reduced level of muscle protein metabolism may limit an individual’s capacity to generate the amino acid glutamine when subjected to stress. This amino acid is utilised primarily by the kidney, intestine and immune system. Thus the response to infection or trauma may be impaired when levels of glutamine are low (Young, 1990a).

1.2.3.1 Energy

The changes in body composition lead to changes in energy metabolism with ageing. The decline in muscle mass is partly responsible for the decline in Basal Metabolic Rate (BMR). The decline in muscle mass, and resultant reduction in maximal capacity to utilise oxygen, also influences the exercise component of energy expenditure.

Both genetic and environmental factors can influence the rate of ageing. Environmental factors such as nutrition in early life and during the years following retirement may have an important role to play in maintaining physical and mental health.
1.3 NUTRITION AND THE ELDERLY

1.3.1 The influence of nutrition on the process of ageing.

Many workers have studied the influence of nutrition on ageing. In some animal models, namely rats and other rodents, there is evidence that modifying the dietary intake of calories, protein and fat can delay maturation and increase lifespan, whilst the animals remain apparently healthy in old age. The biological mechanisms responsible for the effects of underfeeding on life prolongation are not fully understood but may relate to the retardation of the changes in the immune and endocrine system normally associated with ageing. Since these early studies in the 1930s and 1940s, further animal experiments have indicated that overfeeding in early life hastens maturity and shortens life, and that overfeeding after maturity increases the incidence of certain diseases in old age. Very limited accurate information is available to evaluate the influence of life-long dietary habits on the health and longevity in the human population.

There are some aspects in which experimental data from animals has direct relevance to the problems of human nutrition. For example, it has been shown (McCay, 1955) that rats fed from birth on a milk diet have denser bones with a higher calcium content when they die in old age than those fed on a stock diet containing many of the foods commonly eaten by Man.

It is now recognised that nutritional factors can influence not only growth and development before maturity but, as a consequence of this, can also influence the ageing of the mature adult. Certain attributes of old age depend upon the status at the end of the period of growth. Therefore in old people, it is perhaps difficult to distinguish between the effects of nutritional factors which are a result of dietary habits operating for the first time in old age, and those which may have influenced nutritional status many years previously, even in childhood.
1.3.2 Bodyweight and mortality in the aged

Since 1887, life assurance companies have compiled records collating data on height, weight and subsequent mortality of their policyholders. The general conclusion to be drawn from these statistics is that the greater the deviation between actual bodyweight and standard weight (defined as the weight of policyholders who live longest), the greater the risk of death. Mortality patterns do however differ according to both sex and age. Overweight, even when extreme, carries less risk for females; extreme underweight (25 to 30% below standard) carries greater risk for males. In both sexes, overweight is a more serious risk in the younger ages, probably due to the greater risk of developing diabetes, cardiovascular problems and renal disease, whereas underweight carries a greater risk for the older ages. It has been suggested (Andres, 1980) that overweight among the elderly may be more protective than the underweight. This author presented data which indicated that older people with a bodyweight of no more than 130% of standard weight for height, had less morbidity and mortality than those with weight ranges of 75 to 95% of standard.

Some animal studies also suggest a benefit from being obese in later life (Stuchlikova et al., 1975). Three species were studied; rats, mice and golden hamsters. Each species was fed one of three dietary regimens:

1. Dietary restriction in the first and second year of life,
2. Ad libitum diet for the first year and restricted diet during the second year, and
3. Restriction during the first year but allowed food ad libitum during the second year.

The animals which lived the longest were those whose diets were restricted during the first year of life but were allowed free access to ad libitum food for the second year despite the fact that they became obese.
1.3.3 Nutritional needs of the elderly

Relatively little is known about the nutritional needs of the elderly human population, as the existing nutritional information has been mainly extrapolated from studies in younger people. In particular, there is little information regarding the effect of the common chronic diseases of old age on these requirements.

1.3.3.1 Energy

The elderly have a reduced basal metabolic rate and reduced physical activity. Both of these factors contribute to the decrease in energy requirements. Current Estimated Average Requirements for Energy (EAR) (Department of Health Dietary Reference Values, 1991) for women aged 50-74 years are 1900 kcal/day and decrease to 1810 Kcal/day in the over 75 age group. In males, the current EAR declines from 2550 kcal/day up to the age of 59 years, then decreases stepwise until the EAR for the over 75 year age group is 2100 kcal/day. Both of these requirements assume relatively little physical activity.

1.3.3.2 Protein

There is a decrease in total body protein with age (Munro, 1981) with skeletal muscle being primarily affected. Nitrogen balance studies in apparently healthy elderly people and those who were housebound have provided some useful information (Bunker et al., 1987). This study revealed that the healthy subjects were in equilibrium for nitrogen balance on a diet containing 0.97 grammes of mixed protein per kilogramme bodyweight per day, whereas the housebound individuals were in negative nitrogen balance, with a corresponding intake of 0.67 grammes of mixed protein per kilogramme bodyweight per day. The authors were unable to determine whether the negative nitrogen balance observed in the housebound group was due to the low nitrogen intake or to the underlying disease condition.
Earlier nitrogen balance studies have suggested that the amount of protein required to achieve nitrogen balance ranges from 0.57 (Zanni et al., 1979) to over 0.8 grammes egg protein per kilogramme bodyweight per day (Gersovitz et al., 1982). The group studied were a generally heterogenous population including subjects with chronic diseases, many of whom were receiving medication. These factors can all affect nitrogen balance. It is important to recognise that both protein and energy requirements can increase in conditions of physiological stress, including infection, bone fracture, surgery and burns. The nitrogen losses in these situations are directly proportional to the severity of the injury.

Until recently, the recommended intakes of protein have been based not on calculated requirements, but on the fact that people in the UK who are accustomed to taking at least 10% of their energy as protein are not protein deficient. The current figures are based on the estimates of need and make allowances for the fact that only 90% of the protein in food is digested and only 70% is incorporated into the tissues (Department of Health Dietary Reference Values, 1991). Even so figures for EAR and Reference Nutrient Intake (RNI) are lower than 1979 recommendations (DHSS, 1979). Current EAR and RNI for women over the age of 50 years are 42.6 and 37.2 g/day respectively. The corresponding figures for males are 53.5 and 46.5 g/day. The protein RNI for all adults aged 19 years and over is 0.75 g/kg/d.

1.3.3.3 **Vitamins and minerals**

The recommended intake of vitamins and minerals is largely the same for the older age group as for the younger age group. As the requirement for energy decreases in old age, it is more important that this group in the population choose foods which have a high nutrient density.
1.4 NUTRITIONAL SURVEYS OF THE ELDERLY

It is almost 30 years since Exton-Smith and Stanton (1965) investigated the diets of elderly women living alone at home in two North London boroughs. This cross-sectional survey, sponsored by the King Edward's Hospital Fund, revealed a striking decrease in intakes of nutrients with age. All but three of the women studied were aged between 70 and 80 years and the decrease in intakes of women in their late 70s compared with those of women in their earlier 70s was recorded as between 20 and 30% for many major nutrients (calories, protein, fat, iron, Vitamin C). The authors considered the most important cause of the reduction in intake in the older age group to be a rising incidence in disease and physical disabilities, which reduced the appetite and energy expenditure of some of the subjects in the older age group.

This suspicion was confirmed in a longitudinal follow-up of these patients, six and a half years later (Exton-Smith and Stanton, 1975), when it was found that for those women who maintained their health, the intakes of nutrients during the 1962 and 1969 surveys were remarkably similar. In contrast, of those subjects whose health had declined during the years, there was a considerable fall in intake amounting to an average of 20% for protein and 17% for calories.

Further evidence that the low intakes of nutrients are associated with an impairment of health was obtained from a study of the nutrition of housebound old people (Exton-Smith et al., 1972). The intakes of the housebound were compared to those of age-related active people; for the housebound group, there was no apparent decline with age. Indeed, some of the younger people had the lowest intakes. This was because, for the housebound, disability was just as severe and as frequent in the younger as in the older people. Thus, it can be concluded that disease or disability have a greater effect on nutritional intake than does age alone.
The DHSS surveys of 1973 and 1979 are the most recent large studies of nutrient intake and nutritional status of people over retirement age in the UK. (DHSS, 1973; DHSS, 1979) These studies concluded that the majority of the individuals in the elderly population in the UK were attaining an adequate diet (DHSS, 1973). However, a small proportion had been reported to be suffering varying degrees of malnutrition and although the incidence of serious sub-nutrition has been reported as 1.2% (DHSS, 1973), the incidence of less severe, but nevertheless clinical nutritional deficiency, has been reported to be approximately 7% (DHSS, 1979). These studies demonstrate that the incidence of frank nutritional deficiency in the elderly is rare but that some deficiencies, notably those of folate, Vitamin B12 and iron, were found in a small but significant proportion of the population. Those found to be most at risk of nutritional inadequacies were the frail housebound elderly living alone.

More recent evidence of this comes from the small study of Bunker et al. (1987) in which five-day metabolic nitrogen balance studies were carried out in 24 apparently healthy elderly people (age 69.7 to 85.6 years) and a heterogenous group of 20 housebound elderly people (age 69.9 to 85.1 years) with chronic diseases. The daily intake of energy in the housebound elderly was less than half that of the healthy elderly people and the housebound elderly consumed less protein than those who were healthy.

Similar findings were reported in a more recent study by Bunker and Clayton (1989), where the dietary intakes of energy and protein in a group of housebound men and women were found to be approximately two-thirds the intakes of healthy men and women.

The DHSS surveys (DHSS, 1973; DHSS, 1979) also revealed that elderly people over the age of 80 years had an incidence of malnutrition twice that of the total elderly population. These findings are of particular importance
since the past 15 years have seen a marked increase in the number of elderly people over the age of 85 years. There has also been a significant increase in the proportion of elderly who live alone (Social Trends, 1988).

It is interesting to compare the results of nutritional surveys carried out in the UK with those carried out in the United States of America. In the Ten State Nutrition Survey, The National Health and Nutrition Examination Surveys and the Missouri Nutrition Survey (1986-1987), obesity was found to be one of the major forms of malnutrition in the USA population, particularly in middle-aged women, and very few elderly were found to be underweight. Nevertheless, despite attaining an adequate energy intake, these surveys have revealed that substantial numbers of the elderly were lacking in specific nutrients, particularly calories and some of the B group vitamins.

More recently, concern has been expressed over the impact of illness and disability on the nutritional status of the elderly (DH, 1992). There are few data as to the energy and nutrient requirement in health in the elderly population, but the nutritional needs of acute illness, chronic illness or disability are virtually unknown in this group. There was concern that low body weight is so common in chronically ill or disabled old people and the need for research into addressing the possibility of "institutionalised starvation" was recognised (DH, 1992).
1.5 CAUSES OF NUTRITIONAL PROBLEMS IN THE ELDERLY

Inadequate nutrition can result from many superimposed and inter-related factors. Nutritional risk factors can relate to all age groups, but are likely to affect the elderly more severely. This is because the processes of ageing reduces the response and efficiency of metabolic, biochemical and psychological functions. Impairment of taste and smell may occur during the natural ageing process and lead to a loss of appetite. Certain medications have the side effects of causing anorexia. Socio-economic and psychological elements are also important risk factors of malnutrition in the elderly. Being housebound, living alone, having no regular cooked meals, poverty and low social class have all been associated with a poor nutritional status (DHSS, 1979). The important effects of loneliness, bereavement, depression and confusion may remove the enjoyment of, and motivation for regular meals. Appetite, or ability to prepare food may be diminished due to chronic discomfort or pain. There may be a problems with swallowing, or with ill-fitting dentures. It is difficult to eat a good mixed diet in the absence of teeth or if the dentures are so loose or painful that they remain on a shelf or in a glass of water.

Acquiring food may be difficult without assistance; big supermarkets and hypermarkets off motorways are not accessible for many elderly people. Shops are not generally geared to providing portions for just one person, particularly when trying to purchase foods on a limited budget. Lack of nutritional knowledge and susceptibility to inappropriate nutritional information presented in the media may result in money being spent unwisely.

Failure to eat sufficient food, or an inappropriate diet, may not be the only cause of nutritional problems in the older person. Illness can increase the requirement for certain nutrients and there may also be adverse effects of ageing on digestion and absorption which reduce nutrient availability.
The elderly represent a potentially nutritionally-vulnerable at-risk group within the population. As life expectancy has increased and the elderly population has expanded, so the diseases and pathologies associated with ageing have also increased. Inevitably, the elderly are becoming an increasingly-large proportion of not only the population in general but also of the hospital population. A period of hospitalisation is likely to increase the risk of nutritional vulnerability and, if this is prolonged or recurrent, the deterioration in nutritional status can become clinically significant.
1.6 MALNUTRITION IN HOSPITAL

1.6.1 Prevalence of malnutrition in hospital

In the 1970s and 1980s, the prevalence of malnutrition amongst hospitalised patients was well-documented. The incidence of malnutrition is reported to be different depending upon the patient population, the country of study and the criteria used to define malnutrition. Nevertheless, with the reported incidence rate ranging from 19% in elderly women with fractured neck of femur (FNF) (Bastow et al., 1983a) to 80% in adult hospitalised patients from general medical and surgical wards in Thailand (Tanphaichitr et al., 1980), malnutrition is one of the most commonly-acquired conditions throughout the world.

The reported incidence of malnutrition in general surgical patients in the United States of America appears to be similar to that of the general surgical population in the UK. In 1974, Bistrian and Blackburn had found evidence of moderate to severe protein energy malnutrition in approximately 50% of general surgical patients studied. Similar studies from the USA have reported incidence ranging from 31% in general medical and surgical patients of a community hospital (Willard, 1980), to as high as 65% in general surgery patients (Willcutts et al., 1978). Not only has it been recognised that many patients are malnourished upon arrival to hospital but it has also been demonstrated (Bistrian and Blackburn, 1974; Butterworth, 1974; Weinsier et al., 1979) that up to 30% of the patients develop their malnutrition after admission to hospital; in other words, iatrogenic malnutrition. Furthermore, up to 70% of the initially-malnourished patients show a gradual deterioration in nutritional status during their period of hospitalisation (Hill et al., 1977). The authors of this paper considered malnutrition in surgical patients to be a largely "unrecognised problem". After assessing the nutritional status of 105 general surgical patients in a leading UK hospital, the authors found a high frequency of anaemia, weight loss, loss of arm muscle bulk and low levels
of transferrin and albumin. These abnormalities were most common in patients who were still in hospital for longer than a week after major surgery. Moreover, these abnormalities had gone almost entirely unrecognised, even in the patients with sepsis who would have most certainly benefited from improvement in their nutritional status.

A parallel evaluation of nutritional status in medical patients in a USA hospital revealed no less remarkable findings. Nutritional status was assessed in 134 consecutive admissions to general medical services using eight nutrition-related parameters. On admission, 48% of the patients were regarded as having a high likelihood of suffering from malnutrition on admission (Weinsier et al., 1979). These "high risk" patients had a longer stay in hospital compared with those patients regarded as having a low likelihood of malnutrition (28 days versus 12 days). Furthermore, the mortality rate was higher in the high-risk group (13%) compared with only 4% in the low-risk group. Perhaps even more startling was the observation that the likelihood of malnutrition increased in 69% of those patients who were hospitalised for two weeks or more, and six out of the eight parameters worsened in over 75% of the patients who had normal values on admission.

1.6.2 Physiological effects of malnutrition in the hospitalised patient

Both general well-being and the response to treatment are affected by a patient's nutritional status. If malnutrition is prolonged or severe, all human organs, with the exception of the brain, show a reduction in mass. As previously stated, in the kidney, tubular atrophy and swelling of the capsular epithelium can lead to a decreased glomerular filtration rate (GFR). The gut, having a very rapid protein turnover, suffers substantial loss after relatively short periods of decreased nutritional intake and mucosal atrophy is a common feature. The motility of the gut decreases as a result of malnutrition which can lead to malabsorption and bacterial
overgrowth. The effects of malnutrition can also be seen on cardiac and respiratory function which can increase the risk of certain complications such as thrombosis and pneumonia.

Complete uncomplicated starvation in a previously healthy person will lead to death in about two months as has been observed in prisoners who have starved themselves to death. The increased metabolic demand imposed after severe trauma, major surgery, possibly coupled with post-operative infection mean that starvation will lead to an accelerated weight loss and possible death within one month. Although outright starvation is virtually unheard of in the hospitalised patient, semi-starvation or severe under-nutrition can have a serious impact on physiological status and hence recovery.

In a classical study of semi-starvation (Keys et al., 1950), not only was there a reduction in bodyweight of 25% and anticipated loss of muscle strength, but the subjects also became depressed, anxious, irritable, apathetic, introverted and lost mental concentration. Similar observations have been noted in prison camps and during times of famine (Brozek, 1990). These mental and psychological changes are of great clinical importance in the sick patient. Apathy and depression can lead to a loss of will for recovery. Impaired concentration means that the patient may not be able to assimilate information which may be important for effective self-care. A generalised weakness and illness can cause anorexia and an unwillingness or inability to eat.
1.6.3 Consequences of malnutrition in the hospitalised patient

In his classic and frequently-cited study of 1936, it was Studley (1936) who emphasised the clinical significance of malnutrition when he clearly demonstrated the relationship between weight loss and mortality in a group of 46 patients with peptic ulcers. The important observation of this study was that it was the magnitude of weight lost which correlated most significantly with outcome, rather than initial weight or rapidity of weight loss. A weight loss of greater than 20% was associated with a significantly higher post-operative mortality (6/18 compared with 1/28).

In a later, much larger study (Willcutts et al., 1978), strong evidence of the relationship between malnutrition, post-operative infection and mortality was further supported. An assessment of 1,500 surgical patients in a community hospital revealed a malnutrition rate of 65%. Post-operative complications were very low (5%) in the group who showed no signs of malnutrition but increased considerably in the group with evidence of malnutrition. In those categorised as moderately malnourished, the complication rate was 30% and the mortality rate was 20%. In the group regarded as having severe protein calorie malnutrition, these figures rose to 75% and 25% respectively.

It has already been emphasised that the elderly are a particularly nutritionally-vulnerable group and the importance of nutritional status on morbidity and mortality in a population of geriatric rehabilitation patients has been recently highlighted (Sullivan et al., 1990). A prospective study was conducted in 110 consecutive admissions to a geriatric rehabilitation unit (GRU) of a Veterans' Administration Hospital. The risk of developing at least one complication whilst on the GRU was found to correlate with, amongst other factors, serum albumin concentration on admission and amount of weight lost in the year prior to admission. Nutritional variables
also independently correlated with the risk of developing an infectious complication or a major life-threatening complication.
1.7 THE BENEFITS OF NUTRITIONAL SUPPORT

The clinical benefit to be gained from the provision of intravenous (IV) feeding in the 7 to 10 days pre-operative period were well reported in a controlled trial of Heatley et al. (1979). Thirty eight out of 74 patients with a pre-operative diagnosis of stomach or oesophageal cancer were randomised to receive a short course of pre-operative intravenous feeding. The effectiveness of treatment was evaluated by the clinical course and monitored by immune and biochemical parameters. Although there was a significant reduction in the incidence of post operative wound infection in the treatment group, this clinical benefit was not associated with a measurable improvement in parameters of immune function. There were no significant differences in the total length of stay in hospital, nor in the overall change in body weight from admission to discharge. Despite nutritional support, a fall in serum proteins was observed in all patients when initial values were compared with those at discharge. However, a significantly greater number of patients with a low serum albumin on admission (< 35 g/l) developed wound infections in the control group than in the treated group, suggesting that the treatment was of most benefit to those patients who were malnourished on admission. In this study, complications arising from the IV cannulae were common, although generally not serious, and the small benefit derived has to be set against the morbidity associated with IV feeding and the costly and time consuming nature of the therapy.

The recognition of the importance of nutritional status and its ability to influence the clinical course of certain pathological conditions, lead to a number of studies being performed throughout the 1980s designed to evaluate the effects of nutritional support on clinical outcome. One of the leading groups to recognise the close correlation between malnutrition and post-operative complications and mortality, and to recognise the importance of early nutritional support, was Mullen and co-workers. In 1980, they
developed a Prognostic Nutritional Index (PNI), a percentage value derived from the relationship between constant factors and the value of certain nutritional factors. In their study of 145 patients, 50 patients received 7 days' pre-operative nutritional support in the form of total parenteral nutrition (TPN) and 95 did not (control). However, all the patients in the TPN group and 89% of those in the control group received post-operative TPN. The two groups were well-matched with respect to age, sex, diagnosis and PNI score, yet only 23% of the high-risk (PNI ≥ 50%) TPN group of patients developed post-operative complication rates, compared with 56% of the high-risk control group. The mortality rates were 9% and 47% respectively.

A frequently-selected group for study during the early 1980s were patients undergoing major surgery for an underlying malignancy, where the increased metabolic demands of surgery are superimposed upon an individual already likely to have an impaired nutritional status. Naturally, in such extreme cases, the form of nutritional support chosen to evaluate the response was the most intensive and most easily-controlled therapy, that of TPN. The earlier results of Heatley were confirmed in a later, similar trial by Muller et al (1982) where the rates of post-operative wound infection, pneumonia and other major complications, and mortality were lower in the TPN-fed group. Using the same PNI score as Mullen et al. (1980), Smale et al. (1981) investigated 159 patients with malignant disease. Their categorisation of high-risk was slightly broader (PNI ≥ 40%) yet results were similar. Of the high-risk patients, 42% received at least 6 days' pre-operative TPN, whilst the remaining 58% received no pre-operative nutritional support. Despite the fact that some of the control group later received post-operative TPN, the complication rate was 31% in the high-risk TPN group, compared with 66% in the high-risk control group. Mortality rates were 15% and 40% respectively.
It could be argued that the provision of extra calories in the form of IV glucose alone may be all that is required to influence complication rate, but this was proven not to be the case by \textit{Jensen and Ginnerup} (1982). In this study, 20 patients with rectal cancer were randomised into two groups. One group was given intravenous fluid (IVF) with 600 to 1,000 kilocalories from glucose alone but no amino acids. The other group were given TPN containing amino acids, lipids, glucose, vitamins and minerals, for two days pre-operatively and 6 days post-operatively. In addition to this, a maximum of 500 kilocalories per day of liquid diet was also allowed. Both groups were well-matched for age and sex. Of the IVF group, 90\% experienced some kind of post-operative complication and were hospitalised for 25\% longer than the patients in the TPN group.

More recently, workers in Italy (\textit{Giaccaglia et al.,} 1986) have reported on the influence of TPN given to patients over the age of 60 years who were admitted to hospital for hip fracture operations. This was a retrospective study of 190 patients operated on between 1979 and 1984. Eighty patients were given supplementary carbohydrate alone (200-300 kcal/d) and 110 patients were given TPN for their duration of stay in hospital. Mortality at 30 days was 6\% in the carbohydrate-fed group, compared with 3\% in the TPN group. The TPN group also showed a 45\% reduction in complications compared with the carbohydrate-fed group and the duration of stay was shorter, although not significantly. The long term outcome of these patients was not reported, which limits the value of the results.

Parenteral feeding is not only an expensive and high-dependency means of meeting nutritional requirements, it also carries a degree of hazard to the patient. It is therefore important to emphasise that in many cases of clinical malnutrition, gastrointestinal function is normal and consequently attempts should be made to institute enteral, rather than parenteral, nutrition.
The value of early post-operative feeding with elemental diet was investigated by Sagar et al (1979). Elemental diets can be regarded as metabolically superior to conventional enteral feeds because little or no digestion is required and they are almost entirely absorbed in the upper GI tract. An elemental diet is a well-balanced residue-free mixture of all the essential and non-essential amino acids combined with simple sugars, electrolytes, trace elements and vitamins. In this study, 30 patients were allocated to receive either conventional treatment (control group) or elemental diet after major gastrointestinal surgery. The clinical and metabolic course of the patients in the group receiving elemental diet was significantly better than that of controls. The former group lost less weight and had a shorter stay in hospital. The negative nitrogen balance was more pronounced in the control group throughout the 7-day post-operative study period.

The evidence suggests that the provision of nutritional support can improve certain outcome parameters in selected groups of patients. However, in the present financial and political climate, the cost-benefit ratio of any treatment is likely to come under scrutiny and it is important to consider the financial as well as clinical implications of providing nutritional support. One recent report claims that in Britain alone, it has been estimated that a saving of £266 million could be made annually through the targeted provision of nutritional support to hospitalised patients (King’s Fund Centre Report, 1992). This was even when the cost of the nutritional products and the additional nursing time required for their administration and supervision had been taken into account.

It is a well-recognised fact that the proportion of elderly in the western population is increasing, with a corresponding but disproportionate increase in the number of hospitalised elderly. This alone poses a great challenge to the resources and skills of the medical profession. Coupled with the recognition that this group is often in a state of sub-optimal nutrition before
admission to hospital, the challenge is deepened still further. The provision of nutritional support may play a very important role.

In considering the pathology associated with advancing age, there must be two conditions which feature prominently in the mind, osteoporosis and osteoarthritis. As a consequence of this pathology, Britain, along with many other nations, can be described as experiencing an epidemic of orthopaedic surgery, mainly for repair of FNF and for replacement of arthritic hip joints.
1.8 ORTHOPAEDIC PROBLEMS OF THE ELDERLY

1.8.1 Osteoporosis

The most obvious manifestation of osteoporosis is a fracture, most commonly of the hip, wrist or vertebrae. Women are particularly vulnerable to osteoporotic fractures, partly because of the link between osteoporosis and the withdrawal of oestrogen after the menopause, but also because more women than men survive to an age at which osteoporotic fractures occur most frequently. Almost 60% of hip fractures occur in women over the age of 75 years and 80% of all cases occur in women over 65 years (Report of the Royal College of Physicians, 1989). Not only is the incidence increasing with an ever-ageing population, but the risk at all ages is rising (Boyce and Vessey, 1985). A recent report has calculated that over 46,000 people in England and Wales have hip fractures per year and it is estimated that if current trends continue, there will be as many as 70,000 hip fracture patients by the year 1996 (Report of the Royal College of Physicians, 1989). The incidence of hip fractures in many Western countries has increased considerably over the past 30 years, yet this increase has been disproportionate to the increase in the number of elderly. This trend is quite clearly demonstrated in a review of hip fracture patients admitted to the Orthopaedic Trauma Unit of two Nottingham hospitals between 1971 and 1981 (Wallace, 1983). From 1971 until 1977, the rate of increase in incidence was approximately 6% per year, but from 1977 until 1981, this had risen to 10%. In the same four years, the elderly population of Nottingham had increased by less than 2% per year.

Startling statistics reveal that if the 1985 rates of fractures in England and Wales remain unchanged, there will be about 60,000 new cases per year by the year 2016 (an increase of 33%). If the increase in trend continues, i.e., a doubling of incidence every 30 years, there will be about 117,000 new cases a year by 2016 (an increase of 254%). Behind these stark figures, the survivors face not only a great degree of personal suffering from pain and
immobility, but also a reduction in their quality of life in terms of a loss of independence and social isolation. Mortality rates are also high.

Observational studies published over the past 20 years or so, have reported a poor long-term prognosis following hip fracture. Perhaps what is even more important is that over these two decades, the prognosis does not seem to have improved significantly. A study of 202 patients over the age of 45 years who were admitted to hospital in the Atlantic Health Region of Nova Scotia, with fractures of the hip, were followed up over a two-year period. It was estimated that only 63.8% would be alive one year from the date of fracture. This was 70% of the survival rate expected in the general population of corresponding age and sex. For those patients who did survive the first year, the mortality rates returned to that of the normal population. However, the period of greatest mortality was within the first 12 weeks after fracture and the sub-group with the highest mortality were males over the age of 75 years, especially those who were relatively immobile prior to their fracture. In this "dependent" group, the relative survival at one year was only 38% (Gordon, 1971).

A retrospective analysis of the outcomes in 360 patients who suffered fracture of the hip between 1972-1974 in Charlottesville, Virginia, revealed similar findings. One year after injury, 27% of the patients had died and 22% were non ambulatory. The mortality rate was highest during the first four months after injury and continued at a rate in excess of the general population until eight months after injury. Three significant factors were identified as increasing the relative risk of mortality or non-ambulation. These were 1) advanced age (in excess of 60 years), 2) presence of cerebral dysfunction before injury and 3) male sex.

A larger survey was made of 1,592 patients over the age of 50 years who had sustained a fracture of the hip and were admitted to hospital in Copenhagen between 1971 and 1979 (Steen Jensen and Tøndevold, 1979).
in which patients were followed up for five years after the date of fracture. Mortality during the hospital stay was 8.6% which related exclusively to age and sex. The mortality rates three months after fracture was 17% and after six months was 21.5%. After one year, mortality was 27%, after three years 43% and after five years 56%. The survival rate was found to parallel the expected rates after 1.6 years but was found to be higher than expected after 2.8 years.

Similar findings were reported when follow-up data was collected on 675 patients treated for hip fractures in a Norwegian hospital (Dahl, 1980). Data was collected from admissions between the period 1961 to 1970, and the results compared with a series from the same hospital for the period 1948 to 1957. Between the two periods, the number of patients admitted had more than doubled and, somewhat surprisingly, a higher hospital mortality was encountered. However, the four-year survival rate was unchanged. Mortality was again found to be related to the age and sex of the patient and also to the nature and number of associated diseases. Mortality rate was found to be high during the first two months following fracture comparable with the findings of the larger Danish study (Steen Jensen and Tøndevold, 1979) but, in slight contrast, patients surviving to the second month showed no excess mortality during the following four years, having the same life expectancy as the general population.

The factors which are associated with increased hospital mortality have been studied in 342 hip fracture patients in two trauma hospitals in West Virginia (Matheny et al., 1980). The overall mortality rate was 10%; 18.6% in males and 7.0% in females. Higher mortality rates were associated with mental incompetence on admission, mental confusion developing during hospitalisation, cardiovascular disease and pulmonary disease. Mortality rates were also significantly higher in patients who did not have prophylactic treatment with anti-coagulants following surgery.
All of the above studies confine their reports to crude mortality rates but the social prognosis of these patients has more recently become a topic of interest.

A long-term follow-up study of 518 patients with hip fractures was undertaken two-and-a-half years after their operations in a Danish hospital (Steen Jensen and Bagger, 1982). The mortality rate was 35%, the median age of those who died being 83 years. Mortality rate was demonstrated to increase with the degree of social dependence prior to the fracture. Among the patients admitted from home, 45% (127/281) maintained their social function (predominantly those who were regarded as living independently prior to admission), whilst social deterioration was encountered in 47% (132/281) of the patients. In those patients who were discharged to their own homes, social deterioration was encountered in 31% (28/91) of the patients, compared with 45% (44/97) of patients discharged to a convalescent home and 55% (41/74) of patients who were discharged to a rehabilitation clinic.

In Britain, the situation is similar. A smaller study of 105 patients was conducted (Thomas and Stevens, 1974), where the patients were visited at home one year or more after they had been treated for proximal femoral fractures to assess the extent to which their social independence had been affected by the incident. Since the time of fracture, 25% had become more dependent. The principal factors contributing to this outcome were found to be established dependence, greater age at the time of injury and a poor clinical result. Indeed, the authors concluded with the words, "the implications for social services and community care of preventing social impairment justify a more comprehensive investigation." The role of nutrition in this multi-factorial approach may be important. More recently (Greatorex, 1988) reported on an assessment of the outcome of health care in elderly people six months after they had sustained a proximal femoral fracture. All new cases of fracture in persons aged 60 or over admitted to
Stockport Infirmary from September 1984 to September 1985 were studied. Out of the 224 fracture cases followed, up to 182 days after the fracture, 70 patients had died, 64 of whom had died during their initial hospital stay. The main underlying causes of death were bronchopneumonia, myocardial infarction, cardiac failure and pulmonary embolism. The morbidity figures revealed that 65% of these cases had experienced clinical problems in hospital, the most common non-orthopaedic complications being bronchopneumonia, wound infection, ulcer, confusion and thromboembolism. 50% of all the cases had returned to their original places of residence six months after the fracture, but 15% of the survivors (23/154) could no longer live alone after fracture, and in 52% (79/152, 2 not known) the ability to perform normal activities of daily living had deteriorated.

The most promising approach for reducing the morbidity and mortality associated with these fractures has been combined orthopaedic and geriatric care involving a multi-disciplinary assessment of the needs of the individual patient by a rehabilitation team. This approach has long been recognised (Clark and Wainwright, 1966). In 1988, the effectiveness of geriatric rehabilitation care was evaluated in a randomised trial in Sterling (Kennie et al., 1988). 54 patients received regular orthopaedic care (control group) and 54 were randomly selected to be transferred to a peripheral hospital where a general practitioner provided their day-to-day medical attention and a Consultant Physician in Geriatric Medicine attended two ward rounds and one conference of a multi-disciplinary team each week (treatment group). At discharge, significantly more patients in the treatment group were independent in terms of activities of daily living (41 vs. 25), and their median stay was shorter (24 days vs. 41 days). Significantly fewer treatment patients were discharged to institutionalised care (10% vs. 32%) and more to their own homes (63% vs. 38%). These beneficial effects were consistent across a range of ages and mental states. Clearly, both patient and hospital benefited from specialist care provided by this multi-disciplinary team approach.
Orthopaedic surgeons are, by nature, chiefly concerned with ensuring that the technicalities of the surgical procedure attain the highest possible standards for each individual patient. A geriatrician and general practitioner are more concerned with the post-operative medical care and the long-term general care. These two perspectives are equally as important for the overall care of the patient but each will predominate at different stages of a patient's treatment. These two elements form the backbone of patient care, but complementary therapies from a physiotherapist and occupational therapist support this framework and enhance both the rate and goals of recovery. The importance of these complementary treatments is unquestionable. Their influence can be clearly evaluated by defined objective outcome criteria. The value of the hospital dietitian in assessing and enhancing nutritional status in this group of patients is still undervalued in the majority of hospitals. The role of nutrition in influencing outcome may be subtle but nevertheless important and, at present, is largely underestimated.

1.8.2 Osteoarthritis of the hip

Osteoarthritis, or osteoarthrosis as it is sometimes referred to, may produce constant pain, stiffness, deformity and instability in any joint and may gradually make the sufferer's life miserable and limit everyday activities. The weight-bearing joints of the legs, particularly the hips, are most commonly affected and probably have the most serious impact on a person's mobility and quality of life. Treatment involves the replacement of the affected joint with an artificial material known as a prosthesis (the procedure is also known as an arthroplasty). Many types of prostheses have been designed over the years; the common factor being that both acetabulum and femoral head are replaced. Good early results, particularly in relation to total pain relief, are obtained in 90% of cases, leading to a tremendous improvement in quality of life. The three major problems relating to total hip replacements (THR) are the increasing proportion of
elderly people in the population, revision of failed cases and the long waiting times.

As previously described, the epidemic of FNF is overwhelming and in elective orthopaedic surgery a similar epidemic is occurring, with approximately 50,000 operations being performed in Britain annually. The average length of stay in hospital for a patient undergoing a THR is approximately 14 days (Gregg, 1986) and the cost varies from just over £100 to well over £1,000. The condition is more prevalent in women, particularly in those aged 60 and over. Despite the good success rate, not all cases do well. Post-operative complications such as pulmonary embolism can, at worst, be fatal. There is also a significant rate of infection and inevitable late loosening of both the femoral and acetabular components. Infection and loosening will produce a number of cases requiring revision each year, exposing the patients to yet further risks. Although these complications can be attributed to being technical in nature, the course of recovery of these patients can be influenced by many factors. Nutritional status is undoubtedly one such factor, although its influence is perhaps regarded as minor and has therefore not attracted much attention.
1.9 NUTRITION IN ORTHOPAEDIC SURGERY

Most nutritional studies of the hospitalised elderly have encompassed a very heterogenous group of patients involving a large spectrum of medical or surgical conditions. Dietary studies of the elderly patients admitted to hospital for orthopaedic surgery are not easy to find among the published literature but one such study from Denmark (Hessov, 1977) revealed that nutritional intakes of elderly patients admitted for acute orthopaedic surgery rarely met requirements. Over a three-month period, the diets of 31 women and 15 men (average age 74 years) were studied for an average duration of 16 weekdays, the total stay in hospital ranged from 5-56 days. Of the 46 patients, 44 received fewer calories than the recommended dietary allowances (National Research Council 1974) for a healthy person of the same age, and 25 out of 46 consumed less calories per day than would be required for basal metabolism. The mean daily energy intake, assessed by precise weighing of the meals and leftovers, was 1163 ± 341 kcal for the women and 1558 ± 593 kcal for the men. The daily protein intake in 28 of the patients was less than that required for healthy adults (0.8g/kg/day) and none consumed the amount recommended for patients in hospital (1.5g/kg/day). The mean daily intake was 0.7 ± 0.3 g/kg/day for both the men and the women over the period of assessment, equivalent to a mean daily intake of 42 g for the women and 51 g for the men. The low protein intake was attributed to a low overall food intake, coupled with a high consumption of refreshing drinks and snacks providing little nourishment apart from energy. In this study, 22% of the energy intake came from the refreshing drinks and titbits which suggests that refreshing drinks may be a useful medium for providing supplemental nutrition, as they could be enriched with energy and protein.

Similar shortfalls in nutritional intake have been observed in the UK. A survey of the post-operative nutrient intake of elderly women, admitted to hospital for the repair of femoral fracture, revealed that only the intakes of
Vitamin A and Calcium met the DHSS recommendations (DHSS, 1979) for healthy women of the same age. The mean intakes of the major nutrients, energy and protein, as well as Vitamin C, riboflavin, niacin, thiamin and Vitamin D, all fell short of the recommendations (Older et al., 1980). These results suggest that the nutrient intake of elderly female patients who are in hospital following surgery are inadequate for a healthy individual, and therefore are certainly going to be unable to meet the additional nutritional demands imposed by trauma and surgery. These findings are particularly important considering that the elderly represent a group who are at risk of being in a nutritionally compromised status prior to admission.

It appears, however, that not all orthopaedic patients may be nutritionally compromised to the same degree. In a study of 129 patients undergoing orthopaedic surgery (Jensen et al., 1982), the incidence of nutritional depletion as judged by the frequency of abnormal nutritional test results, was found to be the lowest in the group of 36 patients undergoing elective surgery for a THR (28.6%) and the highest in the group of 38 patients requiring emergency surgery for repair of a fractured femur (58.6%). Considering that the average age of the THR group was only 52 years (range 28 to 78 years), and that of the FNF group was 29.5 years (17 to 79 years), such high incidence in a relatively young population is undoubtedly cause for concern.

In hospitalised patients, malnutrition can occur because disease, injury and surgical procedures induce or intensify a pre-existing state of clinical or sub-clinical malnutrition. The mechanism by which this occurs may be through alteration of dietary intake, nutrient absorption, metabolic requirements or a combination of these factors. The increased metabolic requirements of patients sustaining orthopaedic trauma or undergoing major orthopaedic surgery are often overlooked. Cuthbertson first documented that negative nitrogen balance, tissue wasting and weight loss developed in patients with long bone fractures (Cuthbertson, 1930). In more recent years, metabolic
balance studies have confirmed the increased metabolic demands imposed by trauma.

A 10-day study of nitrogen and calorie balance was undertaken in 61 female patients aged 65 to 96 years who had been admitted to Bristol Royal Infirmary with femoral neck fractures (Stableforth, 1986). Of the 61 patients studied, 90% were in negative nitrogen balance post-operatively with a mean 8-day deficit of 411 mgN/kg and all were in negative calorie balance, mean 141 kcal/kg.

In the hypermetabolic state induced by injury, fracture, major operation or infection, adequate supplementation with exogenous nutrient substrates is essential to protect the patient from excessive protein catabolism and to meet the increased energy requirements. Despite these well-recognised relationships, the influence that supplementary feeding may have on this group of patients has received relatively little attention. One well-designed trial which seriously addressed this issue was the randomised control of Bastow and co-workers (Bastow et al., 1983a) in which the benefits of supplementary naso-gastric feeding after FNF were evaluated. A total of 744 elderly women with FNF were classified into three groups according to anthropometric measurements on admission: Group 1 - well nourished, Group 2 - thin, and Group 3 - very thin. Group 1 had a low mortality and a shorter rehabilitation time. The thinner patients not only had a higher mortality and a longer rehabilitation time but also had a lower voluntary food intake, thus widening the nutritional gap still further. A series of 122 patients from Groups 2 and 3 were entered post-operatively into a randomised control trial of overnight supplementary naso-gastric tube feeding (1,000 kcal, 28 g protein) in addition to the normal ward diet. This provision of extra nutrition was associated with improvements not only in anthropometry and plasma proteins but perhaps more importantly also in clinical outcome. The benefits were most apparent in the group of patients who were classified as 'very thin' on admission (Group 3). Rehabilitation
time and hospital stay were shortened and mortality reduced. These results clearly demonstrate the benefits that can be gained from a relatively intensive nutritional support programme. However, the implementation of such a programme for all nutritionally-vulnerable elderly patients admitted to hospital would impose an increased requirement for nursing time and raises the question of patient acceptability. In this study, 14 out of the 64 patients failed to tolerate the naso-gastric tube; thus in this sub-group of 20% of cases, the treatment was not acceptable and was therefore of no value to these patients. Another important finding of this study was that in the patients of Group 2 (thin) the overnight naso-gastric feeding was associated with a small but significant reduction in voluntary food intake, compared with that of controls. This work provides strong evidence for the role of naso-gastric feeding in very undernourished elderly trauma patients who are admitted to hospital for surgery. However, it also highlights several important issues and draws attention to the fact that what is considered the appropriate delivery system for one group of patients may not necessarily be appropriate, nor the most time and cost-effective, for another group.

Many patients may be admitted to hospital in a state of sub-optimal nutrition and consume low quantities of food but be physiologically capable of ingesting, absorbing and metabolising food enterally. In this group, provision of additional nutrients in the form of a simple oral dietary supplement may be the most cost-effective and patient-acceptable means of providing additional metabolic fuel. This thesis documents the research work which was begun in 1986. At this time, most of the nutritional studies reported in the scientific literature were devoted to the evaluation of parenteral and naso-gastric feeds; the population for study most frequently being patients suffering from malignant disease. Studies which reported upon the benefits of sip feed supplements were largely uncontrolled short-term studies which had confined their assessments to the effect of treatment on nutritional variables rather than on clinical outcome.
In a group of hospital patients whose nutritional status is compromised on admission and who are likely to have a reduced food intake during hospitalisation, the provision of sip feed supplements offers a potentially very practical, patient-acceptable and cost-effective means of enhancing nutritional intake.

1.9.1 Sip feed supplements - A valuable nutritional supplement, an expensive replacement, or a wasted effort?
Any potential benefits to be derived from any form of nutritional support can only be realised if the provision of such support is not accompanied by an equal and opposite reduction in normal food intake. Equally, if the supplements are not ingested, their value is worthless.

In the case of intravenous nutritional feeding, this may be the sole source of nutrition, in which case there is little voluntary control over intake. However, in studies where IVN has been supplemental to normal food, very few have reported objectively on the nutrient intake derived from normal foods, but instead have made subjective statements such as, "patients were encouraged to eat and drink as much as possible for a standard ward diet consisting of 3000 kcal and 15 g N ...". Thus it is impossible to calculate the true nutritional intake, or indeed to assess whether there was any increase above what would normally be consumed.

With supplementary naso-gastric feeding, there is some voluntary control over consumption, as was demonstrated by the fact that 14 out of the 64 patients who received overnight NG feeding in the study by Bastow et al. (1983a), refused to tolerate the tube. What is probably more important in such feeding regimens is the influence that they have on normal food intake. In this study, only in group 2 ("thin"), was overnight NG feeding associated with a small, but significant, reduction in voluntary food intake compared with controls. In comparison, an earlier study of the effect of nightly food supplements on food intake in men reported that overnight
intra-gastric feeding of 1000 kcal for 20 days did not reduce normal food intake in the 2 young healthy volunteers studied (Ashworth et al., 1962). The next three subjects were then given 2000 kcal overnight for 5 or more weeks, resulting in a reduction in daily food intake in only one subject. Clearly, care must be taken when extrapolating these results, as factors influencing food intake in young healthy volunteers are very different from those affecting a hospitalised patient.

Fifteen years ago, Banerjee et al. (1978) reported that whole food supplementation with Complan, given as two daily drinks, did not increase the energy, fat or carbohydrate intake of a group of 50 long-stay elderly patients after a period of 14 weeks. It did however, increase the intake of protein, vitamins and minerals. These findings indicate that the supplemented patients selectively reduced their intake of food in their normal diet. Compliance to the supplement was not reported, except for the comment that two patients refused to continue in the study.

In a similar study of eighteen elderly nursing home residents whose food intake was considered "less than adequate", subjects were offered a liquid dietary supplement of Ensure Plus for a period of 30 days. This was associated with an increase in food intake by some of the women, particularly in energy intake. For 28% of the women, the supplements resulted in an increment of 150-746 kcal/d from normal foods (i.e., excluding the supplement). However, for 33% of the women, the daily energy intake decreased by 100-300 kcal/d after supplementation. No appreciable differences were noted in the intakes of the remaining 39%. Considering that the supplement, if consumed in full, would have provided 355 kcal/d, it would appear that for the majority of the women there was an increase in energy intake. However, because there is no reference made to the actual amount consumed, it is difficult to meaningfully interpret these results.
In a treatment group of 26 poorly nourished elderly patients admitted to an acute geriatric ward, the consumption of two sachets of Build Up was "ensured by nursing staff", but unfortunately the workers made no attempt to determine the actual quantity of food consumed by these patients in either group of the study (McEvoy and James, 1982). The authors justified this omission by stating that the study was designed as a practical evaluation and they assumed that any suppression of appetite would be reflected in the results. Although this argument can be accepted in part, it may be misleading to make such assumptions and does not make maximum use of the study design.

The effect of giving a malted drink food supplement to 12 elderly long stay hospital patients for 12 weeks on various biochemical and functional parameters was studied by Katakity et al. (1983). Again, the only comment with regard to compliance was that the drink was given "under the supervision of a senior nurse and the consumption of the drink was recorded on the patient’s chart". Unfortunately, the data from these charts was not reported in the paper and the effect on normal food intake does not appear to have been considered.

One study which did address both the effects of a supplement on normal food intake and comment on compliance was that of Lipschitz et al. (1985), when 12 elderly subjects participating in a Meals-on-Wheels program were identified as being at high risk of protein calorie malnutrition (PCM) and received a liquid dietary supplement of Ensure Plus for 16 weeks. Although the paper reported that the total energy intake increased by 40-50% with the use of the supplements, it is not possible to determine the accuracy of these findings because the method used to determine dietary intake was not specified. It was interesting to note that none of the subjects were able to consume the entire contents of 3 cans, as requested, but nevertheless a 50% intake in calories was achieved with no effect on normal food intake.
Elmstähl and Steen (1987) described clearly the method used to determine food intake in their study. They evaluated the effect of three different dietary supplements in 28 women admitted for geriatric long term care. The results which were presented did show the intake of energy from food alone and from the supplement, although no specific comments regarding compliance were made.

It is recognised that some studies may have been undertaken to address specific practical issues, and after all, it is the clinical result which is important, almost irrespective of how that effect was achieved. However, in order for a reader to review a study and make an informed interpretation of the results, it is necessary for all the facts to be presented in order to enable judgement to be made.

When work is presented with no mention of compliance, how should that be interpreted? Should it be assumed that compliance was 100%, compliance was poor and therefore not reported, or the problem was not addressed. Equally, when there is no breakdown of nutritional data into that derived from the supplement and that derived from normal food, it is difficult to determine the true impact of the supplement. Some patients may benefit from the extra attention, even though the provision of a supplement may reduce their intake of normal foods; in other patients appetite may be stimulated by regular nutritional drinks, thus the intake from normal foods increases. If results from these two people are expressed as a mean value, a great deal of valuable information may be concealed. Individual patients may respond in different ways and important characteristics may be revealed which could result in a better understanding and management of a patient’s needs.

As explained throughout the earlier part of this Chapter, epidemiological studies indicate that the number and proportion of elderly in our society are
increasing dramatically. With this increase, there will be the inevitable increase in the proportion of elderly patients in hospital, particularly patients admitted for orthopaedic hip surgery. The role of nutrition in the recovery and rehabilitation of these patients has been studied to a fairly limited degree and although naso-gastric feeding has been demonstrated to improve the clinical outcome of these patients (Bastow et al., 1983a), this method of nutritional support would not be appropriate for widespread use. The provision of a simple dietary supplement in the form of sip feed (drink) which can be consumed by the patient on a voluntary basis clearly warrants investigation. Because of the large and increasing numbers, and the effect that the condition has on the quality of the patient’s life, elderly female patients admitted to hospital for orthopaedic hip surgery were chosen as an appropriate group for study. This population of surgical patients are a good group for study for several reasons. Firstly, the operation represents a well defined, relatively standard stress occurring at a given time, thus allowing comparison of preoperative nutritional status and nutrition intervention with post-operative result. Secondly, the objective definitions of post-operative progress, as well as morbidity and mortality, are well established end points. Thirdly, this group is becoming an increasingly large proportion of our hospital population.

It is recognised that it is rarely possible to isolate the effects of nutrition from other pathophysiological factors which are likely to contribute to a patient’s clinical outcome, to a varying extent, once nutritional intake has been improved. In the clinical setting, it is arguably unnecessary to separate these factors as the important end point is the overall patient outcome, however in order to interpret the findings of a study it is necessary to consider as many of these factors as possible. Within the limitations of an academic study, a full clinical trial is not feasible. The aim of this work is to investigate some of the methodologies which can be used to evaluate the benefit of sip feed supplements and to identify some of the problems associated with sip feeds in clinical practice.
At the time that this work was planned, the researchers had no knowledge of any similar studies being undertaken. Towards the end of this work however, a similarly-designed study assessing the value of dietary supplements in elderly patients with FNF was published by Delmi et al. (1990) as was a study evaluating the long term effects of nutritional supplement in geriatric patients (Larsson, 1990). These papers will be discussed fully in the discussion section of Chapter 4.
1.10 **AIMS**

The general aims of the work which is presented in this thesis can be summarised as follows:

1. It was considered necessary to undertake a feasibility study enabling the development of a well-designed protocol for a long term evaluation study. During the feasibility study appropriate methods would be established and the personal skills necessary to conduct a long term evaluation study would be developed.

2. The aim of the main study was to evaluate both short-term and long-term nutritional and clinical benefits of sip feed supplement by means of an extended trial.

3. Compliance to nutritional programmes is often unreported but it is generally accepted as being poor. One of the aims of this study was to quantify the rate of compliance in this patient population and to identify the possible factors which may influence compliance.

4. The effect of nutritional intervention on normal food intake is often overlooked. A further aim of this study was to assess the impact of sip feed supplement on the overall nutritional intake and, in particular, the effect on the nutritional intake from normal food.
Chapter 2

Methods and Materials
Chapter 2

METHODS AND MATERIALS

2.1 INTRODUCTION

Before the work described in this thesis was planned in detail, a review of the reported literature was conducted. The aims of this were not only to provide comprehensive background information, but also to allow a critical appraisal of the work already undertaken in the area. Emphasis was placed on the critical assessment of study design, methods of nutritional assessment and the procedures and criteria selected to evaluate clinical outcome.

This chapter will firstly present a general overview of the methods currently available for the assessment of nutritional status. It will then describe the methods which were employed in the studies presented in Chapters 3, 4 and 5. Details of the functional assessments and clinical outcome measures will also be presented.
2.2 REVIEW OF METHODS CURRENTLY AVAILABLE FOR THE ASSESSMENT OF NUTRITIONAL STATUS

Whilst it could be argued that no special diagnostic tool is required to identify a starving patient, more subtle forms of malnutrition can easily go undetected. In the hospital environment, the assessment of nutritional status is likely to take the form of one or more of four types of information: a careful case history may identify an inadequate dietary intake or risk factors which are associated with poor nutritional status; anthropometry may show that a patient has low fat or muscle reserves; systematic clinical examination may reveal signs of specific nutrient deficiencies; biochemical tests may indicate low concentrations of certain nutrients in blood or urine. Recently, sophisticated scanning techniques, which take advantage of the different densities of body tissues, have been used to produce a computerised image and thereby to assess body composition. Although these have become widely available in most hospitals, they are expensive to run, not readily acceptable to the patient and generally in high demand for serious medical conditions. Consequently, the use of these techniques is limited and not practical for the routine assessment of nutritional status.

2.2.1 Subjective clinical assessment

There is no definitive test of nutritional status available. The value of objective measures in the assessment of nutritional status is often questioned because it is difficult to separate the effects of nutrient deprivation from those of the disease process. The subjective clinical assessment of a patient, by an experienced clinician, has been demonstrated to be a reproducible and valid technique for evaluating nutritional status before surgery (Baker et al., 1982). This suggests that carefully performed history taking and physical examination are sufficient for nutritional assessment. In a similar prospective blind study conducted in general
surgical patients, clinical assessment was found to be reproducible and correlated well with objective parameters (Jeejeebhoy et al., 1982). Furthermore, in this study the clinical assessment was able to identify the high risk patient, as far as infection and hospital stay were concerned, to the same accuracy as the objective parameters.

In a larger study of 202 patients undergoing gastrointestinal surgery, it was concluded that both subjective global clinical assessment and serum albumin concentrations were able to predict nutrition associated complications (infections and problems with wound healing).

The limitation of subjective assessment methods are that the observer must have substantial clinical experience in order to make a reliable judgement. A simple Visual Analogue Scale (VAS), which required little training, has been successfully used to measure nutritional status in 94 patients receiving supplemental nutrition on a gastrointestinal unit (George et al., 1988). A good correlation was reported between the VAS and the objective anthropometric measures of percentage ideal weight, MUAC and weight/height². Other measurements showed less significant agreement, particularly TSF and MUAMC. The concordance between measurements made by different nurses was high, indicating that this method could be useful as a nutritional screening tool in the ward situation, however the specificity of such an instrument would be anticipated to be low.

2.2.2 Anthropometric assessments
The main components of body mass are fat and Fat Free Mass (FFM) [also termed Lean Body Mass (LBM)]. The FFM is composed of skeletal muscle (40-50%), non skeletal muscle and soft lean tissues (40-50%) and the skeleton. Anthropometric techniques can be used to give an indication of the amount and proportion of the fat and FFM components. Comparing the
values obtained with population standards can help to identify individuals who are over or under nourished. This method of assessing nutritional status can be particularly useful in the clinical setting where it is important to identify those patients who may already be, or may be at risk of becoming, nutritionally depleted. However, anthropometric assessments are often more valuable to the clinician when used to evaluate changes in nutritional status over a period of time. Regular assessments throughout a patient's period of treatment can help to identify those patients who are at risk of developing complications which could arise following a deterioration in nutritional status. Regular anthropometric assessments can also be used to monitor the effectiveness of a nutritional support regime in those patients who have already been identified as at risk of becoming nutritionally depleted.

Anthropometric techniques are non-invasive procedures, involve relatively little discomfort to the patient, are quick and easy to perform, give results immediately and require minimum equipment and staff time. They do, therefore, offer a practical tool for the assessment of nutritional status, on a potentially large scale, in the clinical environment.

2.2.2.1 Body weight

The measurement of total body weight is a composite measure of all the individual components of the body which together make up the mass of that body (protein, fat, water, carbohydrate, vitamins and minerals). It provides a crude estimate of the body's energy reserves. An individual's body weight can be compared with standard weight for height tables to assess nutritional status. In the elderly hospital patient it may not only be impractical to measure height, but it may also be misleading since there is a decrease in both real and apparent height with advancing age. The patients recalled weight can also be used to give a measure of recent weight loss, however significant errors can arise from using the patient's
recollection of body weight to determine loss (Morgan et al., 1980). Weight index is more useful when used to measure change in body weight over a period of time, a net gain in body weight indicates a positive energy balance, whereas a net loss in body weight indicates a negative energy balance. However, this simple interpretation is open to distortion for a variety of reasons. Since total body weight is the sum of fat, muscle and soft tissues, bone mass and water, an alteration in the amount of any one of these compartments would be reflected by a change in total body weight measurement. Therefore, pathological and physiological factors, such as dehydration, oedema, ascites, tumour growth and surgical procedures can all distort the clinical interpretation of body weight.

Despite the limitations of the use of total body weight, it is a method which is very simple to administer and does provide an indication of a overall change in nutritional status.

2.2.2.2 Skinfold thickness
There is considerable variation in the body fat content between individuals. Body fat consists of essential lipids which are required for normal physiological functioning, protective layers of fat surrounding the internal organs and subcutaneous fat. Only about 1 kg of body fat is essential for physiological functioning, the remainder represents stored reserves which can be drawn upon in time of need and may comprise as much as 70% of total body weight in obese people (Davidson & Passmore et al., 1979). Evaluating the changes in body fat reserves with time will give an insight into the state of energy balance of the individual and the degree of nutritional depletion or repletion.

Skinfold thickness measurements can be used as an index of subcutaneous fat as it is assumed that changes in total body fat are reflected in changes in skinfold thickness. Total body fat (TBF) can be assessed by the
measurement of skinfold thickness at one or more of the following anatomical sites by use of empirical equations, or nomograms (Durnin & Womersley, 1974).

<table>
<thead>
<tr>
<th>Location</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triceps</td>
<td>Measured at the mid point of the posterior aspect of the upper arm.</td>
</tr>
<tr>
<td>Biceps</td>
<td>Measured at the mid point of the anterior aspect of the upper arm.</td>
</tr>
<tr>
<td>Subscapular</td>
<td>Measured just below, and laterally to, the angle of the shoulder blade with the shoulder and arm relaxed.</td>
</tr>
<tr>
<td>Suprailiac</td>
<td>Measured approximately 1 cm above, and 2 cm medial to the anterior superior iliac spine (iliac crest of the mid-auxiliary line).</td>
</tr>
</tbody>
</table>

Subcutaneous fat is not uniformly distributed and if a single site is to be used it is important to choose a site which reflect changes occurring in total body fat. However, practical aspects should also be taken into account when choosing the site and in general, the most easily accessible site is the skinfold thickness of triceps.

Changes in skinfold thickness occur with advancing age, particularly in females (Bishop et al., 1981). A tri-phasic relationship seems to occur between skinfold thickness and age (Hall et al., 1981), with measurements in infants are similar in both sexes with high values, falling rapidly in adolescence then changing only slightly between the ages of 20-60 years. After the age of 60, a dramatic decline appears to occur in both sexes but is more marked in females. It has been suggested that these three phases
may be associated with progressive dehydration, failure to synthesise collagen and frank degradation of the collagen of the dermis \((Hall\ et\ al.,\ 1981)\). This decrease in subcutaneous fat could also be explained by the redistribution of fat that occurs with advancing age, from the subcutaneous regions to central body and internal organs \((Kubena\ et\ al.,\ 1991)\). Low anthropometric variables in elderly women have been attributed to low levels of nutrient intake \((Morgan\ et\ al.,\ 1986)\). However, other workers have concluded that measurement of subcutaneous fat in individuals with low body fat may not be a sensitive indicator of nutritional status \((Frisancho,\ 1974)\).

Observer error is an important limitation in the measurement of skinfold thickness. If sites have first been located and marked by an experienced observer, then measurements by a relatively inexperienced observer have been reported to be in agreement. However, if the sites were not marked, significant discrepancies have been reported, the inexperienced observer generally obtaining a higher value \((Burkinshaw\ et\ al.,\ 1973)\). Inter-observer error has been reported to be the greatest for obese patients than for lean patients \((Bray\ et\ al.,\ 1978)\).

### 2.2.2.3 Mid Upper Arm Circumference (MUAC)

Muscle mass serves as a "store" of protein reserves for the body and the measurement of MUAC and calculation of Mid Upper Arm Muscle Circumference is assumed to reflect changes in total body protein stores.

### 2.2.2.4 Mid Upper Arm Muscle Circumference (MUAMC)

Mid upper arm muscle circumference (MUAMC) is defined as the circumference of the muscle surrounding the small, central core of bone \((Gurney\ &\ Jelliffe,\ 1973)\) and is derived from the measurement of mid upper arm circumference (MUAC) and triceps skinfold thickness (TSF), from the following equation:
MUAMC = MUAC - (π X TSF)
(All measurements must be in the same units)

This equation assumes that the cross-section of the arm is both circular and uniform. It also ignores the core of bone. The fact that the arm is not uniform, either cross sectionally, or longitudinally, can give rise to errors in measurement if the tape measure is slightly displaced. This could account for some of the intra and inter observer error.

There are several limitations with this method, such as the effect of physiological factors. The measurement of MUAC will be influenced by changes in fluid balance. Oedema will lead to an inaccurately high calculation of MUAMC and dehydration will lead to an inaccurately low calculation of MAUMC. However, MUAMC has been demonstrated to be a convenient method of assessment of protein calorie malnutrition in surgical patients (Young et al., 1978).

2.2.3 Body fat composition by Underwater weighing
The proportion of fat in the body can be determined using this method. The density of human fat can be taken to be 0.900, the density of lean body mass cannot be so accurately determined but is taken to be 1.10. If \( x \) is the percentage of fat in the human body:

\[
\frac{100}{d \text{ (body)}} = \frac{100 - x}{1.10} + \frac{x}{0.90}
\]

\[
x = \frac{495}{d} - 450
\]

where \( d \) = body density
The density of the human body can be determined by first weighing the body in air and then in water. If \( M = \) mass of the body and \( V = \) the volume, then:

\[
d = \frac{M}{V}
\]

The volume of the body is determined by displacement. The difference between the weight of the body in air and the weight when submerged in water is equivalent to the weight of the water displaced. The volume which corresponds to this mass of water can then be determined by dividing the density of water at the time of the underwater weighing. The underwater weight is corrected for the upthrust of residual air in the lungs by measuring lung volumes at the end of submersion, using Nitrogen or Helium re-breathing. The calculation of \( x \) gives the amount of fat in the body.

However, this method is invasive, unlikely to be readily accepted by elderly and is not practical to perform in surgical patients.

2.2.4 Total body \(^{40}\text{K}\)

The body of a healthy 65 kg man contains approximately 80 mmol of potassium in extracellular fluid and approximately 3500 mmol in the tissues (80% of which is in the skeletal muscles). The measurement of total body potassium gives a measure of cell mass. \(^{40}\text{K}\) is a naturally occurring isotope and is present in a small but constant fraction (0.0019%) of the potassium throughout nature; it emits gamma rays which can be measured in a whole body counter. The store of potassium in bones is negligible. Measurement of natural gamma emissions allow estimation of total body \(^{40}\text{K}\) and thus of cell mass and lean body mass. Body fat content is then calculated by difference.
Again this method is unlikely to be readily accepted by the elderly as it requires sitting in a darkened room for about 30-40 minutes, and it is not practical for surgical patients. It is also a very expensive method.

2.2.5 Neutron activation
This method uses the fact that gamma rays are emitted from the nitrogen and hydrogen nuclei in the body when they are bombarded with neutrons. Gamma counters can be used to measure these emissions, from which conversion factors can be applied and the total body protein determined.

2.2.6 Tritium or deuterium labelled water (H\textsubscript{3}O)
This method is based on the dilution principle. Total body water can be assessed by dilution of the stable isotope deuterium, or the radioactive isotope tritium. The half life is only a few hours, therefore it does not stay in the body for long. The isotope is simple to administer, in a glass of water, and a blood sample taken after a defined period of time measures the dilution of the isotope. The assumption is made that the label reaches all non-fat compartments and care must be taken to account for the water lost in metabolism during the period of equilibration. Assumptions are also made about the specific gravity of lean tissue and the proportion of bone. Limitations of this method include the expense of the isotopes and a mass spectrometer. It has not yet been validated in the elderly population, although the method has potential benefits.

2.2.7 Bio-electrical impedance
The bio-electrical impedance, or electrical conductivity, of the body is related to the proportions of body fat and lean tissue. Empirical equations have been derived by comparing the results with those obtained for established methods. The elderly have different concentrations of intra- and extra-cellular fluid, compared with young adults. Specific equations
have been developed for use in the elderly (Deurenberg et al., 1990). This method is portable, relatively cheap, convenient and requires little training. This method may, therefore, be a useful assessment tool of body composition changes in the elderly, although the results should be interpreted with caution in individuals with conditions affecting fluid balance.

2.2.8 **Infra-red reactance**

This is a relatively new method, originally developed for animal husbandry. The method depends upon the transmission of infra-red light through the body, at two different wavelengths. As the beams pass through the fat and lean tissue, change in absorbance is related to amounts of fat and lean tissue. This method has been found to underestimate systemic fat, when compared with isotope dilution and underwater weighing (Conway et al., 1984) and has not yet been validated in the elderly.

2.2.9 **Dual Energy X-ray absorptiometry**

Dual energy X-ray absorptiometry (DEXA) is a rectilinear scanning X-ray system which, by measuring the attenuation of two distinct peak X-ray energies, can calculate the amount of soft tissue, adipose tissue and bone mineral present in the patient. The equipment produces a radiographic image of the patient. The radiation effective dose equivalent is very low, equivalent to well under a chest X-ray. The running costs are high, making it unsuitable for routine use.

2.2.10 **Computerised Tomography (CT) Scanning**

Computerised X-ray tomography has been used for some time to measure changes occurring in body segments such as the thigh; however, the radiation dose is too high for routine use.
2.2.11 Magnetic Resonance Imaging (MRI)
This method differs from other scanning techniques in that it uses a magnetic field to polarise all the atoms of the body in one direction. When the magnetic field is removed, the atoms return to their original position, with a release of energy. Measurement of this energy release can be used to produce an image of the various densities of the body tissues. However, the method is very expensive and requires the patient to lie in the equipment for a period of time which is unacceptable to many patients, making it inappropriate for routine use.

2.2.12 Biochemical assessments
The observer errors involved in the measurement of muscle protein and its relative lack of sensitivity to change, limits its application as a marker of nutritional status. The assessment of plasma protein concentrations is a simple and rapid procedure that can be repeatedly performed. Plasma visceral proteins (such as albumin, transferrin, thyroxine-binding pre-albumin and retinol binding protein) have important functions as hormone, substrate and vitamin carriers. Other plasma proteins, such as the acute phase reactants (a-1-glycoprotein, a-1-antitrypsin, C-reactive protein, a-2-macroglobulin, haptoglobin, caeuloplasmin and fibrinogen) play an important role in the defence of the host during inflammatory conditions. They stimulate the development of the immune response and participate in wound healing. Serum albumin and retinol binding protein are frequently used as indicators of nutritional status (Carpentier et al., 1982).

2.2.12.1 Serum Albumin (ALB)
The diagnosis of protein calorie malnutrition is often based upon the measurement of a low concentration of hepatic transport proteins such as serum albumin (ALB). The mean serum albumin values and ranges of the elderly population have been shown to be identical to those considered normal in a younger population (Leask et al., 1973). It has been concluded
that a decrease in serum albumin in the elderly is usually the result of chronic malnutrition rather than ageing (Goodley, 1989). Serum albumin has a relatively long half-life of approximately 20 days and so is used as an indicator of long term protein intake. However, the plasma concentration of proteins is affected not only by the balance between synthesis and breakdown, but also by changes in the amount and distribution of body fluids and capillary permeability. Such changes in fluid distribution occur after surgery, thereby making albumin an unreliable indicator of nutritional status in the immediate post operative period. Even in an individual with stable fluid balance, the long half life means that it is slow to respond to changes in dietary intake.

2.2.12.2 Serum Retinol Binding Protein (RBP)
RBP is known as a rapid turnover protein, with a short half life of approximately 2 days. This makes it a suitable plasma protein for evaluating the short term effects of nutritional therapy as it can be a more sensitive indicator of recent nutritional state than albumin. However it may be less useful as an index of long term nutritional status.

2.2.13 Functional assessments
Traditional methods of the assessment of nutritional status, including anthropometric and biochemical indices, are based on the measurement of static values. These measurements provide no indication as to whether important biological function is adversely affected by loss of visceral protein muscle or fat. Functional tests are therefore regarded as providing more clinically relevant information than the measurement of body components or circulating proteins.

2.2.13.1 Hand grip strength
The protein status of an individual can be monitored by anthropometric and biochemical assessments, but these measures do not reveal the functional
effects of a changing protein status. If protein status has deteriorated, it is reasonable to assume that a degree of atrophy of muscle fibres has taken place, but the clinical effects of this may not be evident. If weakening occurs in the muscle structure of the lungs, the individual is likely to have an impaired cough reflex and therefore be more prone to chest infections. In a patient who also has an impaired immune response, the risk of a chest infection developing into pneumonia is a serious one, particularly in the elderly.

The most practical method of assessing muscular function is to determine the hand grip strength of an individual. However, the subjective element of this procedure should be taken into consideration. A low hand grip strength in female geriatric patients has been reported in those patients who subsequently died (Phillips, 1986). The cause of death in a large proportion of these patients was chest infection. It has been suggested that a low grip strength may be able to identify a population at risk because of associated malnutrition, generalised muscle weakness and immunodeficiency (Phillips, 1986). In a 5 year longitudinal study in older people, hand grip strength has been reported to decline with advancing age and also to be lower in those who subsequently died (Milne and Maule, 1984).

2.2.13.2 Mental function
Low scores obtained on a mental testing have been correlated with low hand grip strength and, it has been suggested that chronic mental impairment may be a cause of malnutrition (Phillips, 1986).

A marked increase in the prevalence of dementia has also been observed with advancing age, from 1.6% of men and 2.2% women under the age of 70, to 12% men and 19.8% women aged 70 years and over (Milne and Maule, 1984). In the females aged 70 years or over, the mean hand grip strength
was significantly less in those regarded as demented. However, the distributions of the male and female demented groups lie wholly within the distributions of the groups who were mentally normal.

Routine mental testing of all elderly patients admitted to hospital has been suggested, since it may aid diagnosis and management (Denham and Jefferys, 1972). In this study of patients admitted to the Geriatric Unit of the Northwick Park Hospital, a questionnaire was adapted from one used at Tooting Bec hospital, and was renamed the "Camden Questionnaire". The questionnaire comprised of 16 questions relating to past and current affairs and took about 3 minutes to administer. A follow-up of these patients revealed that, after six months, 50% of the severely demented patients remained in hospital compared with 2% of those patients regarded as having a normal mental status.

The Clifton Assessment Procedures for the Elderly (CAPE) is widely used in the assessment of elderly patients (Pattie and Gillear, 1979). A short survey version has also been developed which comprises the "Information-Orientation" and "Physical disability" sections of the original version. This shorter version has been validated in the elderly and has been shown to distinguish groups of elderly who had been selected to represent different levels of impairment and dependency (McPherson et al., 1985). The Information-Orientation section may be an appropriate alternative to the Camden Questionnaire.

2.2.14 Nutrient intake data
Clinical judgement, anthropometric, biochemical and functional measurements of nutritional status can all be used to identify the already malnourished patient. A detailed assessment of an individual's dietary
habits can be used to identify those who may be at risk of malnutrition, but in whom functional or compositional deficits are not evident.

In order to provide accurate information the appropriate method of dietary assessment should be chosen.

2.2.14.1 Dietary surveys
Dietary surveys are the method of nutritional assessment used in epidemiology studies which relate dietary practices to disease states. The information is useful in identifying a relationship between diet and disease states and for identifying particular groups of the population who may be a nutritionally at risk group. Dietary surveys do not, however, provide an accurate representation of an individual's nutritional intake.

2.2.14.2 24 hour dietary recall
A retrospective self-reported evaluation of an individual's dietary intake over the previous 24 hours is useful in providing information on the range of food items consumed by an individual and hence, the intake of nutrients. However, the selected day may not be representative of an average day and the method does not take into account daily variations in intake. Although useful in indicating the types of foods consumed, the method is limited to providing only semi-quantitative information regarding amount of food consumed as it relies on descriptive terminology.

2.2.14.3 Interview technique to establish "usual" food intake
A structured interview, by a trained professional, can establish the pattern of usual food intake of an individual. The main limitation of this method is that the estimation of portion sizes is only semi-quantitative and the degree of accuracy is determined by the skills of the interviewer and the cooperativeness of the interviewee.
Recently, a computer-assisted interview on diet and risk factors has been developed which has incorporated a nutrient analysis programme for the calculation of usual dietary intake (Smucker et al., 1989). This system has obvious benefits in terms of efficiency, but would not be practical for use in individuals who are unfamiliar with computer systems, for example the elderly.

2.2.14.4 **Weighed food intake**
Weighed food intakes are usually performed over a period of between one and seven days, dependent on the nutrient being calculated (Marr and Heady, 1986; Thompson et al., 1988).

The principle can be employed in several different ways. Weighing all foods before they are eaten can provide accurate dietary information but is very demanding on the individual and can lead to deviations in normal food selection. The weighing of duplicate meals can provide accurate information regarding nutrient intake, but is labour intensive in terms of preparation. In an environment where food choice is restricted and portion sizes are controlled, the weighing of "standard" portion sizes can reduce the work load considerably. Documentation of the foods selected and weighing of the plate waste can offer a practical and accurate method of determining nutrient intake for patients in hospital.

2.2.14.5 **Diet records using household measures**
The weighing of all food eaten is time consuming and requires a high degree of motivation from the subject if accurate data are to be collated. A more "user friendly" alternative has been developed which involves recording foods consumed in household measures (Cade, 1988). This method has been reported to give comparable results, to within 10% for the macro nutrients (energy, protein, fat and carbohydrate) when compared with weighed
intakes (Cade, 1988). This method could be useful in studies of food intakes of the elderly in the community.

2.2.14.6 **Food frequency questionnaires**

Self administered food frequency questionnaires have been reported to be useful tools for measuring both group and individual intakes of a variety of nutrients (Pietinen et al., 1988). However, when food frequency questionnaire data have been compared with daily dietary records, mean energy intakes estimated from the questionnaire have been found to be significantly greater than mean energy intake calculated from the records (Flegal et al., 1988). The discrepancies were reported for both serving size and frequency of consumption. A similar report observed that discrepancies between the food frequency questionnaire and quantitative methods (24 hour recalls, 3, 10 or 14 day dietary records) were due to the actual intake being overestimated by the food frequency questionnaire for categories of frequent consumption and underestimated for categories of infrequent consumption (Boeing et al., 1988). In contrast, Lockie et al. (1988) reported that the intakes of energy and several nutrients calculated using typical portion weights of a food frequency questionnaire were less than those derived from a weighed inventory.

2.2.14.7 **Food Recording Electronic Device (FRED)**

The hand completion of food records is one of the practical limitations of this method. The introduction of computer read bar codes has led to their application in the recording of food items by use of a code book and a key pad to key in the weight of the food portion. This method has been validated against seven day weighed food intake assessments with a high correlation (Stockley et al., 1986). Although not appropriate for use in certain population groups, this method has great potential for further development.
2.2.14.8 The use of food photographs
This relatively new method of food intake analysis has reduced the input required from the individual recording their intake. Each individual is asked to photograph each meal and record details of cooking methods and concealed ingredients, such as sugar. The photographs are then displayed alongside previously prepared "standard" slides and a weight is given to each food (Elwood and Bird, 1983a). When used correctly, the method gives good correlation with weighed food records (Elwood and Bird, 1983b).

2.2.15 Combination indices
It could be argued that if a battery of nutritional assessment procedures are employed, nearly all patients will have at least one abnormality. That they are all at risk of malnutrition would seem unlikely, and the predictive power of each individual assessment may vary considerably. This has led some researchers to develop indices which take into account the predictive power of several parameters. One example of this is the Prognostic Nutritional Index (PNI) developed by Mullen et al., (1980). Following the extensive preoperative nutritional assessment of 161 surgical patients and evaluation of subsequent outcome, a predictive linear equation was developed. The PNI was calculated as the percent risk of post operative complications in an individual patient and was derived according to the following formula:

\[ \text{PNI \% risk} = 158 - 16.6 \times \text{ALB} - 0.78 \times \text{TSF} - 0.2 \times \text{TFN} - 0.58 \times \text{DH} \]

where:

- ALB - serum albumin (g/dl)
- TSF - triceps skinfold thickness (mm)
- TFN - serum transferrin (mg/dl)
- DH - maximum cutaneous delayed hypersensitivity reactivity to any of three recall antigens (defined on a scale of 0, 1 or 2)
Although this approach received considerable interest in the mid 1980's and its use was widely studied in patients undergoing gastrointestinal surgery, it was not shown to be any more powerful than some single objective methods of assessment, in predicting at risk patients (Baker et al., 1982).
2.3 SUMMARY

As the relationships between nutrition and health become more recognised and understood, so the need for tools of assessment and monitoring of nutritional status will increase. Subjective clinical judgements will continue to be important in identifying the severely malnourished patient, but more subtle degrees of malnutrition could go largely undetected. More sensitive methods of assessment are required to detect lesser degrees of malnutrition and to monitor the effectiveness of nutritional therapy. There are several sophisticated techniques now available for the accurate assessment of the composition of the body, making their application particularly suitable for research studies. However, their use in the routine clinical setting is restricted because of the high financial running costs, the amount of time required of the patient to conduct the test and the practical limitations involved in the transport of patients to the site of equipment. In addition, such procedures often cause unnecessary anxiety to the patient. For clinical application, the methods employed must be inexpensive, portable, quick and easy to perform with the minimal discomfort to the patient. To monitor the effectiveness of nutritional intervention, the method must be sensitive to change in nutritional status. Anthropometric assessments fulfil many of these criteria but could be criticised with respect to sensitivity to change, such that they cannot reflect changes until they have affected the tissue mass. The simultaneous assessment of biochemical indices of protein status can offer earlier insight into the changes which occur in protein status before they affect the tissues. It is not only important to address what is happening to the fat and lean body mass of an individual, it is also important to assess the functional impact of any changes, particularly in terms of muscle function, and, whether clinical outcome is affected.

Anthropometric measures of body weight, MUAC, TSF and the plasma proteins albumin and RBP have been reported as being lower on admission
to hospital in those patients who subsequently died (Kemm and Allcock, 1984; Volkert et al., 1992). The predictive ability of these assessments would, together with their relative ease of measurement, make them useful markers in a study aimed at evaluating the effect of supplemental nutrition in hospital patients.
2.4 METHODS USED IN THE PRESENT INVESTIGATIONS

The methodologies chosen to assess and monitor the nutritional status, functional capacity and clinical outcome of a population of elderly female patients admitted to hospital for orthopaedic hip surgery is presented below.

The criteria used to select these methods were the accuracy, reliability, sensitivity and validity of the technique balanced against the practical limitations, patient acceptability and financial cost.

It should be remembered that there is no universally accepted reference standard method for the assessment of nutritional status. It is likely that a combination of both subjective and objective assessments will remain the criteria adopted in the clinical setting.

The procedures reported below are the methods which were employed for identifying the nutritionally vulnerable elderly orthopaedic patient, on admission to hospital, and to monitor the effects of supplemental nutrition.

2.4.1 Nutrition Risk Questionnaire

At present there is no single universally accepted reference standard method of determining nutritional status. The methods employed for the purpose of a research study may not be practical for regular use in the routine clinical setting. If a nutritional screening procedure could be adopted as one of the routine assessments made on admission to hospital, nutritional support could be effectively targeted. Such a procedure would need to be simple, quick and easy to perform without any detailed specialist training, and be able to successfully categorise patients as "high" or "low" risk individuals. A simple tick list questionnaire of nutritional-related risk factors has been used to identify a group of "high risk" elderly orthopaedic patients. The course of recovery of the group receiving a score of eight or greater was considered less favourable than the group receiving a score of less than
eight (Olleranshaw, 1986). The duration of stay in hospital was significantly greater in the high risk group, deteriorations in anthropometric indices were greater and nutritional intakes were significantly lower during the period of hospital stay (energy, protein, calcium, iron, vitamin C and vitamin D). The patient population used in this observational study were elderly male and female patients admitted to the general medical and surgical wards of the Royal Surrey County Hospital. The Nutrition Risk Questionnaire (NRQ) was used for the purpose of identifying nutritionally vulnerable patients in the studies presented in Chapters 3, 4 and 5 of this thesis. A detailed evaluation of the use of the NRQ in identifying at risk elderly patients was undertaken by a co-investigation in a parallel study to the present. Investigations and the results obtained have subsequently been reported (Lumbers, 1993). A copy of the questionnaire can be found in Appendix II.

2.4.2 Anthropometric assessments

Anthropometric assessments were employed to monitor changes occurring in body composition over the period of study.

2.4.2.1 Body weight

i) Introduction

Due to pain or immobility, it was not possible to weigh all patients on admission, but an attempt was made to weigh as many patients as possible during their duration of stay in the acute hospital. For those patients in whom it was not possible to obtain body weight, the patient's recollection of their weight was recorded. This recall weight was not used in the analysis if it was considered, by subjective evaluation, to be inaccurate.
ii) Equipment
For the determination of body weight whilst in hospital, the ward chair balance scale (Marsden UK Ltd) was used. After discharge from the acute hospital, a portable electronic digital scale was used (Salter, model 980). The maximum weight which could be determined accurately was 136 kg (21 st) and the minimum was 12 kg (1 st 11 lbs). The graduation was 0.5 kg (1 lb).

iii) Procedure
Patients were weighed in their night clothes or light day clothes whilst in hospital and, in light day clothes following discharge. No shoes were permitted, although light slippers were allowed providing they were worn for all the assessments.

iv) Reference values
There are no universally accepted standards for the ideal weights of elderly people. Although absolute weight is an important parameter, serial measurements made over a period of time are more useful in monitoring the changes in nutritional status of an individual.

v) Repeatability
The repeatability of the procedure was assessed by one investigator carrying out repeat measurements on the same subject. The coefficient of variation for intraobserver repeatability was found to be ± 0.5%.

2.4.2.2 Triceps Skinfold Thickness (TSF)

i) Introduction
The measurement of skinfold thickness is a direct measurement of the subcutaneous adipose tissue thickness, and as such can provide a simple and inexpensive measurement of energy and nutritional status. The triceps
skinfold thickness (TSF) measurement was used in this study to assess and monitor adiposity.

ii) Equipment
Triceps skinfold values were measured using Holtain skinfold callipers (Nottingham Rehabilitation Ltd).

iii) Procedure
The TSF measurement recorded was the mean of three readings taken at the mid-point of the non-dominant upper arm between the tips of the acromial and olecranon processes using Holtain skinfold callipers. The skinfold is gently pinched from the underlying muscle just below the point of application of the callipers between the thumb and the forefinger so that the pressure applied to the point of measurement is from the callipers and not the fingers. The callipers are designed to exert a constant pressure over a wide range of jaw openings, although the measurements are less accurate when the value is above 20mm. The triceps skinfold thickness was measured with the patient's arm hanging loosely at the side. Occasionally, when the patient was confined to bed with the patient supine the measurement was taken with the arm folded across the chest.

iv) Reference values
Whilst normal anthropometric ranges have been derived from the study of the elderly (Morgan et al., 1986), there is still no consensus as to the most appropriate standards. In the present study, the main purpose of this assessment was to monitor changes in fat stores that occur in individuals over time, and to compare the relative losses and gains of the patients receiving nutritional supplements, with those not offered the supplements. The triceps skinfold measurement was also used in the calculation for determining mid upper arm muscle circumference.
v) Repeatability
An intraobserver error (coefficient of variation) of 4% and an interobserver error of 10% were obtained when five repeat measurements were carried out by two investigators, on the same subject, on the same day.

2.4.2.3 Mid Upper Arm Circumference (MUAC)

i) Introduction
Mid upper arm circumference (MUAC) is used in the calculation to determine mid upper arm muscle circumference (MUAMC). Both are anthropometric indicators of skeletal muscle protein mass.

(i) Procedure
The mid upper arm circumference was measured in centimetres at the same level as the triceps skinfold thickness, using a non-stretchable tape measure. Care was taken not to pinch the arm and to take the measurement at the mid-point of the upper arm, as the arm is fusiform in shape.

(ii) Repeatability
The intraobserver error (coefficient of variation) for this measure was extremely small (< 1%) due to the simplicity of the method.

2.4.2.4 Mid Upper Arm Muscle Circumference (MUAMC)

(i) Procedure
MUAMC was calculated from measurements of TSF and MUAC, by the formula previously described.

The equation given in section 2.2.2.4 assumes that the arm and muscle are circular, when in fact they are more elliptical. Also it is assumed that the bone area is negligible. Again it must be noted that care must be taken to take
these measurements at the mid-point; even slight displacement from the mid point may affect serial measurements significantly. The variations in the measurements of the skinfold thickness and arm circumference by different individuals can result in up to 33 per cent error in arm muscle area, (Mullen et al, 1979). This can be reduced to 10 per cent by using the same observer.

(ii) Repeatability
The intraobserver error (coefficient of variation) for MUAMC was 5%. This is expected since the repeatability of the method is dependent upon the TSF measure which has a higher CV, particularly in elderly subjects.

4.2.4.3 Biochemical assessments

i) Introduction
In the studies described in Chapters 3 and 4, a 5-10 ml sample of venous blood was obtained at various time periods. Aliquots of serum were obtained and stored at -20 °C and analyzed in batches.

Serum albumin determinations were made during the study described in Chapter 3, and both serum albumin and serum retinol binding protein (RBP) determinations were made during the study described in Chapter 4.

2.4.3.1 Serum Albumin (ALB)
Serum albumin measurements were made using a manual spectrophotometric method based on the binding of bromocresol green to albumin.
(i) Principle
Albumin is effective in binding a wide range of endogenous and exogenous materials including bilirubin, salicylate and fatty acids. Anionic dyes such as methyl orange and bromocresol green (BCG) also bind avidly to albumin. At pH 4.0 the BCG dye displaces most substances bound to albumin, to form a dye-protein complex which exhibits optical properties different from the free dye. Human serum albumin reacts specifically with BCG to form a stable green colour complex with an absorption maximum at 632 nm.

(ii) Reagents

1. BCG Reagent

70 mg of BCG (Sigma Chemical Co. Ltd.) was dissolved in 5 ml of NaOH. The solution was made up to one litre with 0.06M succinate buffer (pH 4.1) and 0.7g of Brij 35 detergent was added.

2. Albumin standard solution

A stock solution of albumin (10mg/ml) was prepared by dissolving bovine serum albumin (Sigma Chemical Co. Ltd.) in 1% NaCl. On each day of analysis a series of standards covering the range 1-10 mg/ml was prepared using 1% NaCl as a diluent. All serum samples were diluted 1:5 in 1% NaCl prior to analysis.

(iv) Linearity
The plot of absorbance against standard albumin concentration was linear over the range 1-10 mg/ml and all samples analyzed fell within this range. The mean regression coefficient for a series of five standard runs was 0.99 with a SD of 0.03 (CV = 0.04%).
(v) Procedure
150 ul of diluted test serum were mixed with 2.5 ml of BCG reagent and mixed thoroughly. A reagent blank was prepared with 150 ul of 1% NaCl in place of the sample. Standard samples were included in each assay run and treated in an exact manner to test samples. Samples and standards were kept at room temperature for 10 minutes and absorbance read against the reagent blank at 632 nm using a Kontron Uvikon 860 spectrophotometer. All samples were analyzed in duplicate and samples re-run if duplicate values differed by > 0.04 mg/ml. Quality control serum, (Boehringer Ltd.), were included in each assay run. If these fell outside of ± 5% of the predicted values the samples were re-analyzed using fresh reagent.

2.4.3.2 Serum Retinol Binding Protein (RBP)
Serum RBP measurements were carried out using a radial immunodiffusion assay (RIA) method employing the use of commercially prepared immunodiffusion plates.

(i) Principle
Immunodiffusion plates containing an agar gel to which specific antiserum to RBP has been added were used to determine the concentration of RBP in biological samples; by measurement of the diameter of the antigen-antibody precipitate formed by reaction of the sample RBP (antigen) with the agar gel antibody.

(ii) Reagents

1. LC-Partigen Immunodiffusion plates (Behring Ltd)
Plates are prepared using agar gel with rabbit antisera to RBP. Sodium azide (1g/l) and sodium p-ethyl-mercury-mercapto-benzene-sulphonate (0.1 g/l) are added as preservatives.

2. RBP Standards

A stock solution of RBP (108 mg/l) was prepared in 1% NaCl. On the day of analysis a range of standards (12-72 mg/l) was prepared by dilution of the stock solution in 1% NaCl.

(iii) Linearity

The plot of \((\text{diameter})^2\) of the precipitates against standard RBP concentration was found to be linear over the range 18-72 mg/l. The mean regression coefficient of a series of five standard runs analyzed on different days was found to be 0.98 with a SD of 0.06.

The regression line equation from the standard curve was shown to be:

\[ y = 0.50x + 20.29 \]

where \(y = (\text{diameter})^2\) (mm) and \(x = \text{RBP standard concentration (mg/l)}\)

(iv) Procedure

The plastic immunodiffusion plate was removed from the aluminium container and allowed to stand at room temperature for 5 minutes to allow evaporation of any condensation water that may have entered the wells.

Each plate contained 20 sample wells. Serum (20 ul) was transferred to the wells using an accurate Gilsen pipette set to 20ul dispensing volume.
Samples were plated in duplicate. After loading, the plates were allowed to stand open for 10-20 minutes, then closed with the plastic lid and left to stand at room temperature.

The diameters of the antigen-antibody precipitates were read after a diffusion time of 3 days. The diameters can be read with an accuracy of 0.1 to 0.2 mm. For accurate readings a measurement ruler was used with illumination of the plate from the side and with the plate placed on a dark background.

Standards were treated in an exactly similar manner with a set of standards run for every 40 samples.

If duplicate samples differed by 0.5 mg/l, repeat determinations were carried out. If sample values were obtained above the normal range (30-60 mg/l) the determinations were repeated using a more dilute sample (e.g. 1:2).

The interassay coefficient of variation for analyses carried out on separate days over a month was found to be 6.6 percent.

All serum samples for the individual patients collected over a period of time were kept stored at - 20 degrees C., until the assay could be performed on all samples simultaneously.

(v) Calculation of results
The concentration of RBP in individual samples was calculated from the regression equation above where:

\[
RBP \text{ (mg/l)} = \frac{(diameter)^2 - 20.29}{0.50}
\]
2.4.3.3 Routine hospital biochemical and haematological assessments

i) Introduction
On admission to hospital, routine measurements of haemoglobin, white cell count and creatinine were made. The results of these were documented for the patients studied in Chapter 4.

2.4.3.3.1 Haemoglobin
The measurement of haemoglobin concentration was carried out in the Department of Haematology, St Lukes Hospital Guildford, using the Coulter JS Instrument.

Normal range: 12.0 - 16.5 g/dl (females)

2.4.3.3.2 White Cell Count
Total white cell count was determined using standard cell counting cytology. Measurements were carried out in the Department of Haematology, St Lukes Hospital Guildford.

Normal range: 4 - 11 $\times 10^9$/l

2.4.3.3.3 Platelet count
Platelet count was determined using standard cell counting cytology. Measurements were carried out in the Department of Haematology, St Lukes Hospital Guildford.

Normal range: 150 - 400 $\times 10^9$/l
2.4.3.3.4 Creatinine

The determination of serum creatinine concentration was performed in the Department of Clinical Biochemistry, St Lukes Hospital Guildford, using the standard Jaffe method. This method is based upon colourimetric changes occurring as a result of the reaction of creatinine with picric acid. Measurements were made using a Monarch Analyzer, with a reported coefficient of variation of 0.5%.

Normal range: 60-125 umol/l (0.7-1.4 mg/100ml)

2.4.4 Functional assessments

2.4.4.1 Hand grip strength

(i) Equipment
In the feasibility study (Chapter 3) measurements of maximal voluntary handgrip strength were made using a handgrip transducer which required a power supply. Units of measurement were mmHg. In the long term evaluation study (Chapter 4) a portable strain gauge handgrip dynamometer was used (Nottingham Rehabilitation Group). Units of measurement were lb/in².

(ii) Procedure
Grip strength was measured using the hand of the non-dominant arm usually with the patient in a sitting position. Three readings were taken as a maximum of three attempts and the highest value chosen. Accurate measurement of grip strength was not possible in some patients because of local disease of the hand, due to arthritis and previous Colles fracture.

(iii) Repeatability
The repeatability (coefficient of variation) of the measure, in single subject over one day, was shown to be 2%.
2.4.4.2 Mental Function

In the feasibility study (Chapter 3) mental function was assessed by a memory and awareness test, using the modified version of the Northwick Park Mental Function Test (Hodkinson, 1972). A copy of this assessment can be found in Appendix II.

For the long term study a cognitive assessment scale was chosen. This involved using the twelve-item Information/Orientation and the Mental Ability sections of the Clifton Assessment Procedures for the Elderly (Pattie and Gillear 1975, 1977). To complete the Information/Orientation section, the patient was asked a series of 12 questions relating to their personal details, their environment, current affairs and their perception of date and time. In the Mental Ability section, the patient was asked to count, to recite the alphabet, to write their name and to read a list of words. A copy of this assessment can be found in Appendix II.

2.4.4.3 Mobility and degree of functional independence

2.4.4.3.1 Time taken to achieve mobilisation with the aid of a walking frame, crutches or sticks

The number of days, post operatively, that the patient took to reach each of these stages of mobilisation were recorded.

2.4.4.3.2 Modified VISICK index

The patient is assessed by the following criteria:

0  Fully active, able to carry on all pre-disease performances without restriction.

1  Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature.
2 Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about greater than 50% of waking hours.

3 Capable of only limited self-care, confined to bed or chair greater than 50% of waking hours.

4 Completely disabled, cannot carry out any self-care. Totally confined to bed or chair.

5 Dead.

2.4.4.4 Location of discharge and independence of living
The pre-admission way of living, location of discharge from the acute hospital, and location at subsequent assessments, were documented according to the following categories:

Living independently

In warden controlled accommodation

In the care of relatives

In a residential home

In a convalescence hospital

Transferred to a private, or more local, hospital

Readmitted to the acute hospital (RSCH)
2.4.5 Clinical outcome parameters

Objective clinical end points and morbidity data were used to determine clinical outcome.

2.4.5.1 Duration of stay

The total duration of stay in hospital is an accepted clinical outcome parameter.

2.4.5.1.1 In the acute hospital

The total duration of stay in hospital was recorded, from the day of admission to the day of discharge. However, as patients admitted for emergency surgery (for repair of a fractured femur) usually underwent surgery on the same day as admission, but patients admitted for elective surgery usually underwent surgery the day after admission, bias could arise in the data. Therefore duration of stay in the acute hospital was documented in two ways:

i) Day of admission to day of discharge

ii) Day of surgery to day of discharge

2.4.5.1.2 In the convalescence hospital

Some patients required a further period of stay in a convalescent or rehabilitation hospital, before being discharged to a more independent environment. The total number of days spent in the second hospital were recorded.

These hospitals were all within a 30 mile radius of the acute hospital, being Cranleigh, Haslemere, Holy Cross and Milford Hospitals.
2.4.5.2 Complication rates
The number (and percentage) of patients experiencing complications during the period of study were recorded. Data have been presented for infections, repeated falls and technical complications.

2.4.5.2.1 Infection rates
Details of patients experiencing a urinary tract infection, chest infection (including those which developed into pneumonia) or wound infection were recorded.

2.4.5.2.2 Re-admission to hospital
Details of the patients who were readmitted to hospital during the period of the study were documented.

2.4.5.2.3 Repeated falls
The number of patients who reported a fall following discharge from the acute hospital was recorded.

2.4.5.2.4 Technical complications of the surgical procedure
Some patients experienced complications which were related to the technical aspects of the initial surgical procedure. If this resulted in either an extension of the duration of stay in hospital or a readmission to hospital, it was considered important to document this.

2.4.5.3 Mortality
The number of patients who died in the period of acute hospital stay, or in the period between subsequent visits following discharge, were recorded.

2.4.6 Nutrient intake data
An estimation of nutritional intake was made on defined days throughout the period of study. In Chapter 4, nutrient intake was determined by the
24 hour dietary recall method. In Chapter 5, a more precise method was employed by the weighing of food portions and subsequent plate waste.

2.4.6.1 **24 hour dietary recall**

An assessment of the patient’s previous day’s food intake was made by personal interview. In hospital, if the patient had difficulty in recalling this information from memory, the hospital menu cards were used as a prompt and additional information was elicited from the ward staff. In the post discharge period of assessment, where possible the subject’s friends or relatives were able to assist.

The patient gave a subjective description of the portion size of each food, in terms of "small", "medium" or "large", or household measures. Published standard portion weights were then used to quantify the amount (Crawley, 1988).

2.4.6.2 **Weighed food intakes**

The portions of food served to patients whilst in hospital are of a standard weight. A list of the weight of a standard serving was provided from the hospital catering department and sample weight-checks were performed regularly. The meal trays were kept and the plate waste weighed. This weight was then subtracted from the standard portion weight to determine the weight of food consumed.
Chapter 3

Feasibility Study
Chapter 3
FEASIBILITY STUDY

3.1 INTRODUCTION

A critical review of the literature, published during the previous twenty years, revealed that most of the studies designed to evaluate the potential benefits of nutritional support had been concerned with assessing the value of more invasive forms of nutritional intervention, namely parenteral and naso-gastric feeding. (Heatley et al., 1979; Muller et al., 1982; Bastow et al., 1983a; Giaccaglia et al., 1986) Such feeding regimens are not only invasive and restrictive for the patient, but they are also considered expensive to implement with regard to both the cost of the materials involved and the medical time required for effective management. These regimens are also recognised as carrying a certain degree of hazard for the patient. The risk of developing septicaemia with intravenous infusions is arguably a small, but serious, possibility. The incorrect positioning of a naso-gastric tube may be considered unlikely, but nevertheless is possible, and could result in the fluid being delivered directly into the lungs. For these reasons, such feeding regimens would not be considered an acceptable option for large-scale use, such as in the relatively high percentage of nutritionally-vulnerable hospitalised patients who may benefit from a period of nutritional support. Considering these limitations, the use of naso-gastric feeding should be restricted to patients for whom the ingestion of normal foods is minimal; and parenteral feeding should only be used where the gut is non-functional and nutrients given enterally would not be utilised.

In contrast, the voluntary ingestion of sip feed supplements can offer a nutritionally complete, convenient way of meeting the daily nutrient requirements and may be particularly useful in sick elderly patients in
whom appetite and normal motivation for eating may be suppressed. The provision of sip feed supplements is not associated with the problems of potential systemic infection, high cost, or high demand for nursing time and would therefore offer a more practical solution for large-scale use. Such methods are less invasive and would therefore appear to be more acceptable to the patient. All these advantages considered, it is somewhat surprising that more attention has not been paid to the investigation of the value of sip feed supplements, used to complement the intake of normal foods in the hospitalised patient.

Only a small number of studies have evaluated the use of sip feed supplements in the elderly and many of these have confined the study groups to either those patients living in the community (Lipschitz et al., 1985), chronically-ill long-stay geriatric patients (Banerjee et al., 1978; Katakity et al., 1983; Elmstahl and Steen, 1987) or nursing-home residents (Harrill et al., 1981). At the time this work was planned, only one group of workers had addressed the problem in patients of an acute stay geriatric ward (McEvoy and James, 1982). More recently, other workers have investigated the role of oral dietary supplements (Delmi et al., 1990; Larsson et al., 1990) which will be discussed fully in Chapter 4.

These studies varied considerably in protocol design, the number of subjects studied and the outcome variables which were used to determine the value of the supplements. The number of evaluable patients completing the studies ranged from 12 in the study of Katakity et al. (1983), to 51 (McEvoy and James, 1982). Four of the studies (Harrill et al., 1981; Katakity et al., 1983; Lipschitz et al., 1985; Elmstahl and Steen, 1987) were of longitudinal design, where the subjects were observed for a period of time before the implementation of the nutritional support programme and each subject served as their own control. Again there was a great variation in duration
of the observational period - the shortest being two days (Harrill et al., 1981) and the longest being three weeks (Lipschitz et al., 1985); One group of workers (Elmstål and Steen, 1987) compared the value of three different supplements, but only two groups (Banerjee et al., 1978; McEvoy and James, 1982) used a control group, where patients were randomly allocated to either a treatment or a control group. All of the patients studied by Banerjee et al. (1978) were observed for a period of fourteen weeks, following which the treatment group received a further fourteen weeks of an oral nutritional supplement, whereas the patients in the treatment group of McEvoy and James (1982) received only four weeks of nutritional supplementation; the duration of the treatment period in each of the other studies was between these two values.

In each of the aforementioned studies, the supplements were provided on a daily basis, either as one bolus drink, or divided into several portions, yet the level of supplementation which was offered varied considerably from 204 kilocalories and 9 grammes of protein per day (Katakity et al., 1983) to 600 kilocalories and 36.4 grammes of protein per day (McEvoy and James, 1982). It is an important omission to note that not one of the authors reported seriously on the degree of compliance to these regimens.

Most previous workers have concentrated on determining changes in biochemical and/or haematological and anthropometric indices to evaluate benefit (Harrill et al., 1981; McEvoy and James, 1982). Some have combined these indices with either assessments of subjective clinical criteria (Banerjee et al., 1978), functional physiological or mental performance tests (Banerjee et al., 1978; Katakity et al., 1983) or assessments of immune function (Lipschitz et al., 1985). Few attempts have been made to assess the impact of a nutritional support programme upon the indices of clinical outcome without which clinical and economic benefits cannot be adequately
evaluated. In the concluding words of the authors of one paper, "additional studies are needed to provide data pertaining to the ultimate goals of nutritional supplementation of the elderly: increased function and decreased morbidity and mortality" (Harrill et al., 1981).

It could be argued that clinical outcome is difficult to assess over a short term, especially as most of the patients living in the community or in nursing homes or long-stay geriatric wards will have relatively stable medical conditions and therefore any change in condition would be subtle. Indeed, it is the patient who is admitted to hospital for an acute period in whom assessment of clinical outcome may be the most appropriate measure of effectiveness of nutritional support. The naso-gastric feeding study of Bastow et al., (1983a) clearly demonstrated the impact that a relatively intensive feeding program can have on certain indices of clinical outcome. This study involved the supplementary overnight tube feeding of randomised controlled groups of women, admitted to hospital with a fractured femur. The provision of this nutritional support was associated with improvements not only in anthropometric and plasma protein levels, but also in clinical outcome - a reduced rehabilitation time and a shortened hospital stay.

In summary, the design of the previously reported studies which have used sip feed supplements can be criticised for a number of reasons: most have been limited to evaluating benefit in relatively small numbers of patients; few have used appropriate control groups; the periods of assessment have been very short; and the indices used to evaluate effectiveness often bore little relation to the clinical value of the supplements. A comprehensive study of the benefit of sip feed supplementation, in which the effectiveness of sip feed supplements is assessed in terms of anthropometric and
biochemical measurements as well as clinical outcome, was therefore indicated.

In designing such a study, it was important that an appropriate population or sub-group was chosen. Elderly women admitted to hospital for orthopaedic hip surgery were regarded as an appropriate study group for two main reasons. Firstly, they represented a potential nutritionally-vulnerable group of patients and, secondly, this group represented an increasingly large proportion of patients admitted to hospital for an acute stay. Due to the limited literature available and the relative inexperience of the investigator in the planning, design and conduct of such studies, it was decided that a feasibility study should be performed. This was considered necessary in order to provide data relevant to issues of the study design and to appreciate the logistics of conducting such a study within the resources and limitations of a post-graduate project. The specific objectives of the feasibility study were defined as follows:

1. To determine the number of patients eligible for recruitment.
2. To determine the rate at which eligible patients could be recruited.
3. To assess patient compliance to the programme and therefore to anticipate the time required to recruit the desired number of patients.
4. To evaluate the initial benefits of sip feed supplements given to patients during their period of stay in hospital.
5. To define the markers to be used throughout the study and to define appropriate times of assessment.
6. To define clinical outcome criteria.
7. To refine and evaluate monitoring procedures.
The intention of this Chapter is therefore not to present a detailed analysis of the results obtained but to outline and comment upon the major observations. The main aim of this work was to serve as a feasibility study enabling the main trial to be planned more effectively.
3.2 PATIENTS, PROCEDURES, ASSESSMENTS AND EXPERIMENTAL DESIGN

The study was carried out on the two orthopaedic wards of the Royal Surrey County Hospital (RSCH), Guildford. Ethical consent was obtained from the Hospital Ethics Committee; informed verbal consent was obtained from all patients before participating.

3.2.1 Patients

**Inclusion Criteria**
1. Female patients
2. Aged 60 years or over
3. Admitted to the RSCH for orthopaedic hip surgery, either as emergency admissions (for fractured femur) or elective admissions (for hip replacement).

**Exclusion Criteria**
1. Patients with mental impairment (temporary or long-standing), with whom reliable communication was not possible; for example, patients with senile dementia or severe temporary post-operative confusion.
2. Patients who refused consent to participate.

3.2.2 Procedures

On admission (within 48 hours), each patient was categorised into a high-risk (HR) or low-risk (LR) group, according to the score obtained from their response to a nutrition-risk questionnaire (NRQ). This score is termed the nutrition-risk score (NRS). Those patients with a NRS of 8 or greater were termed HR and those with a score of less than 8 were termed LR. A copy of the NRQ can be found in Appendix II; details of the background to the questions is described in Chapter 2 (Methodology) and a comparison of the
outcomes of the HR and LR groups has been presented elsewhere (Lumbers, 1993). On each ward, the patients categorised as HR were alternately allocated to either a group who would be offered the supplement (S) or a group who were not offered the supplement (NS). Those patients allocated to the supplement group were asked to consume between two and three cans of Ensure (Abbott Laboratories) per day. This amounted to a daily intake of 500-750 kilocalories of energy and 17.6-26.4 grammes of protein, in 16 - 24 fl.oz (500-750 mls). The period of supplementation was initiated as soon as possible after surgery and continued throughout the duration of the stay in hospital. The full nutritional composition of one can of Ensure is shown in Appendix III Table A3.1.

Compliance to the regimen was defined as the consumption of an average of at least one can of Ensure per day, from the start of supplementation until discharge from the acute hospital.
3.3 ASSESSMENTS
Further details of the method are described in Chapter 2 (Methodology).

3.3.1 Anthropometric assessments
Measurements of triceps skinfold thickness (TSF) and mid upper arm circumference (MUAC) were made on all patients on admission and repeated at weekly intervals until discharge. From these two measurements, mid upper arm muscle circumference (MUAMC) was derived using the formula described in Chapter 2.

It was not possible to obtain body weight on admission to hospital for those patients who were emergency cases, due to a fractured femur, because of the obvious pain on movement. Traction was applied in the casualty department and not removed until surgery and it would not have been practical to insist that all patients be weighed on a bed weighing scale. Patients undergoing elective surgery were usually admitted to the ward the day before surgery was scheduled and therefore it was possible to obtain an admission body weight for most of these patients as part of their routine nursing care plan. Practical difficulties were encountered when pain and immobility were so extreme that the patients could not sit on the ward chair scales. Bodyweight was therefore determined either on admission, or at some time during hospital stay, wherever possible.

3.3.2 Biochemical assessments
A blood sample (5-10 mls) was taken at the time of admission and again during the week prior to discharge, for the determination of plasma albumin concentration.
3.3.3 Functional assessments

Voluntary hand grip strength (vHGS) was determined on all patients on admission and at weekly intervals until discharge. The procedure involved squeezing a strain gauge with the non-dominant hand, to maximum grip strength. The grip strength generated an electrical signal which was displayed by means of an anchored needle on a semi-circular scale.

Mental function was assessed using a modified version of the Northwick Park Mental Function Test (Hodkinson, 1972) within three days of admission. The maximum score obtainable was 20.

3.3.4 Clinical assessments

Clinical outcome was evaluated according to specific outcome variables; namely, length of stay in hospital and time taken to achieve mobilisation with the aid of a walking frame. An assessment of the patients' overall independence at discharge was made on the basis of their discharge location, (i.e., whether the patient was able to return to their own home on discharge from hospital, or whether they required a further period of care in a relative's home, convalescence hospital or residential home). An outline of the experimental design is shown in Figure 3.1 and a summary of the assessment procedures is shown in Table 3.1.
Table 3.1: Feasibility Study

Summary of assessment procedures

<table>
<thead>
<tr>
<th></th>
<th>Within 48 hours of admission</th>
<th>Within 72 hours of admission</th>
<th>Weekly intervals until discharge</th>
<th>Within the week prior to discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td>NRQ</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TSF</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>MUAC</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>vHGS</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Mental Function</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serum Albumin</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Clinical Outcome</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>
3.4. **OUTLINE OF EXPERIMENTAL DESIGN**

A diagrammatic representation of the experimental design is shown in Figure 3.1.

![Diagram of experimental design]

**Completion of Nutrition Risk Questionnaire (NRQ)**

- **Nutrition Risk Score (NRS)**
  - **NRS < 8**
    - Low Risk (LR)
    - \( n = 20 \)
  - **NRS ≥ 8**
    - High Risk (HR)
    - \( n = 36 \)

Alternate Allocation

**Non-Supplement (NS)**

- Non-Supplement Admission Pairs of S-NC sub group (NS-NCP)
  - \( n = 7 \)

**Supplement (S)**

- Supplement Non-Compliers (S-NC)
  - \( n = 7 \)

**Retrospective "Pairing"**

- Non-Supplement Admission Pairs of S-C sub group (NS-CP)
  - \( n = 11 \)

**Self Selection**

- Supplement Compliers (S-C)
  - \( n = 11 \)

**Fig 3.1** Recruitment and Categorisation of patients into the feasibility study.
3.5 **STATISTICAL ANALYSIS AND PRESENTATION OF RESULTS**

Results are presented for each group as *mean values ± standard deviation* for *n* number of measurements. Group means were compared and differences assessed by the unpaired Student t-test. Changes within groups over a period of time were assessed by the use of the paired Student t-test. In order to normalise the distribution, data for TSF and MUAMC underwent log transformation prior to analysis. Statistical tests were considered significant at the *p* < 0.05 level. Data for the supplement (S) and non-supplemented (NS) groups were compared irrespective of compliance, using the "intention to treat" approach. However, in order to ascertain whether daily supplementation was associated with nutritional benefit, data from some of the anthropometric measurements underwent additional analysis, using only the results from the supplement-compliant group (S-C). In order to prevent a bias arising in the results from the self-selection effect, data from the corresponding non-supplement "admission pair" to the non compliant patients (NS-NCP) were also excluded from the analysis of the non-supplement group. This retrospective pairing was achieved by sequentially numbering the patients recruited into each of the two groups, ie: patients allocated to the S group were numbered from one onwards, as were patients recruited into the NS group. This system enabled each patient in the S group to have a corresponding "admission pair" from the NS group, so that the NS group could be retrospectively assigned to either the NS-CP or NS-NCP sub group. (See Figure 3.1 for explanatory flow diagram). Thus for some data, results are described in two ways; firstly the results are presented for comparisons of the S and NS groups, using the "intention to treat" analysis and, secondly some results are presented for the comparison of the S-C and NS-CP sub groups.
3.6 RESULTS

3.6.1 Patient details
Over the 6 month recruitment period (December 1986-May 1987), a total of 36 HR patients were recruited into the study. Alternate allocation of the patients resulted in 18 women being allocated to the non-supplement group and 18 into the supplement group. Of the 18 allocated to receive the supplements, only 11 complied to the regimen, giving a compliance rate of 61%. Details of the patients are given in Appendix III, Table A3.2.

In addition to the 36 HR patients, 20 patients were categorised as LR and were also studied for the duration of their stay in hospital. The results for these LR patients are not presented here since the data are not directly relevant to the purpose of this Chapter. However this does highlight that 64% of this patient population are categorised as HR, nutritionally vulnerable, individuals.

3.6.2 Admission Characteristics
A summary of the admission characteristics (age, reason for admission, NRS) of the HR supplement (S) and the HR non-supplement (NS) groups is presented in Table 3.2.

3.6.3 Admission Measurements
Admission measurements (TSF, MUAC, MUAMC, hospital body-weight, VHGS, mental test score and plasma albumin) for the HR supplement and the HR non-supplement groups are presented in Table 3.3.
Table 3.2

Summary of the admission characteristics of the HR (S) and HR (NS) groups.

<table>
<thead>
<tr>
<th></th>
<th>High Risk Supplement (HR-S) (n=18)</th>
<th>High Risk Non Supplement (HR-NS) (n=18)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years)</strong></td>
<td>80.7 ± 19.4</td>
<td>81.8 ± 9.4</td>
</tr>
<tr>
<td><strong>Type of Admission</strong></td>
<td>Emergency: 15 (83%)</td>
<td>Emergency: 14 (78%)</td>
</tr>
<tr>
<td></td>
<td>Elective: 3 (17%)</td>
<td>Elective: 4 (22%)</td>
</tr>
<tr>
<td><strong>NRS</strong></td>
<td>9.9 ± 2.0</td>
<td>9.7 ± 1.5</td>
</tr>
</tbody>
</table>

Results are presented as mean values ± sd.

There were no significant differences between the two groups for any of the characteristics recorded.
Table 3.3

Admission measurements of the High Risk supplement and the High Risk non-supplement groups.

<table>
<thead>
<tr>
<th></th>
<th>High Risk Supplement (HR-S)</th>
<th>High Risk Non-Supplement (HR-NS)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TSF (mm)</strong></td>
<td>14.7 ± 4.8 (n=18)</td>
<td>12.8 ± 6.1 (n=18)</td>
</tr>
<tr>
<td><strong>MUAC (cm)</strong></td>
<td>26.8 ± 3.8 (n=18)</td>
<td>27.5 ± 4.8 (n=18)</td>
</tr>
<tr>
<td><strong>MUAMC (cm)</strong></td>
<td>22.3 ± 2.8 (n=18)</td>
<td>23.2 ± 1.9 (n=18)</td>
</tr>
<tr>
<td><strong>BODY WEIGHT (Kg)</strong></td>
<td>51.2 ± 12.2 (n=8)</td>
<td>60.2 ± 20.4 (n=4)</td>
</tr>
<tr>
<td><strong>vHGS</strong></td>
<td>14.3 ± 6.4 (n=18)</td>
<td>13.9 ± 8.0 (n=18)</td>
</tr>
<tr>
<td><strong>MENTAL TEST SCORE</strong></td>
<td>12.7 ± 4.5 (n=16)</td>
<td>11.6 ± 4.9 (n=18)</td>
</tr>
<tr>
<td><strong>SERUM ALBUMIN (g/dl)</strong></td>
<td>38.0 ± 5.7 (n=9)</td>
<td>39.0 ± 8.0 (n=7)</td>
</tr>
</tbody>
</table>

Results are presented as mean values ± sd.
There were no significant differences between the two groups for any of the parameters measured.
3.6.4 Changes in Anthropometry and serum albumin from Admission to Discharge

The changes in anthropometric measurements (TSF, MUAC, MUAMC) and serum albumin from admission to discharge for the HR-S and HR-NS groups have been analysed using the "intention to treat" approach. These results are summarised in Table 3.4. The results for the anthropometric measurements are also presented after the further division into the supplement compliant (S-C) and non-compliant (S-NC) sub-groups with their corresponding admission pairs from the non-supplement group (Table 3.5.)

**Table 3.4**

Summary of the changes in anthropometric measurements from admission to discharge in the HR-Supplement and the HR-Non-Supplement Groups.

<table>
<thead>
<tr>
<th></th>
<th>High Risk Supplement (n=18)</th>
<th>High Risk Non-Supplement (n=18)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Change in TSF (mm)</strong></td>
<td>+ 0.28 ± 2.96</td>
<td>- 0.56 ± 2.9</td>
</tr>
<tr>
<td><strong>Change in MUAC (cm)</strong></td>
<td>- 0.03 ± 0.81</td>
<td>- 1.15 ± 1.02</td>
</tr>
<tr>
<td><strong>Change in MUAMC (cm)</strong></td>
<td>+ 0.17 ± 1.08</td>
<td>- 1.04 ± 1.28</td>
</tr>
<tr>
<td><strong>Change in serum Albumin (g/dl)</strong></td>
<td>- 0.1 ± 7.7 (n=8)</td>
<td>- 3.1 ± 4.9 (n=7)</td>
</tr>
</tbody>
</table>

Results are presented as mean values ± sd.

Within group changes: **P < 0.01  ***P < 0.001
The group receiving the nutritional supplements (HR-S) demonstrated no significant change in any of the parameters measured from admission to discharge. In contrast to this, the patients who did not receive nutritional supplements (HR-NS) demonstrated a significant decline in both MUAC ($p < 0.001$) and MUAMC ($p < 0.01$). The decline seen in TSF did not reach statistical significance.

Serum albumin did not change significantly from admission to discharge, in either the S or the NS group, although a trend of decline was observed in the NS group.
Table 3.5
Summary of the changes in anthropometric measurements from admission to discharge in the HR-Supplement (Compliant & Non-Compliant) and the HR-Non-Supplement (Admission pairs to Compliant & Non-Compliant) Groups.

<table>
<thead>
<tr>
<th></th>
<th>HR-S-C (n=11)</th>
<th>HR-S-NC (n=7)</th>
<th>HR-NS-CP (n=11)</th>
<th>HR-NS-NCP (n=7)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in TSF (mm)</td>
<td>-0.26 ± 2.78</td>
<td>+1.15 ± 3.02</td>
<td>-0.36 ± 2.90</td>
<td>-0.87 ± 3.00</td>
</tr>
<tr>
<td>Change in MUAC (cm)</td>
<td>0.0 ± 6.8</td>
<td>+0.22 ± 0.94</td>
<td>-1.25 ± 1.02</td>
<td>-0.99 ± 1.00</td>
</tr>
<tr>
<td>Change in MUAMC (cm)</td>
<td>-0.05 ± 0.85</td>
<td>+0.38 ± 1.29</td>
<td>-1.16 ± 1.46</td>
<td>-0.84 ± 0.88</td>
</tr>
</tbody>
</table>

Results are presented as mean values ± sd.
Within group changes: * P < 0.05 ** P < 0.01

When the supplement and non-supplement groups were sub-divided into compliant and non-compliant (and their corresponding pairs from the non-supplement group), the results were similar. The group who complied to the supplement regimen (HR-S-C) demonstrated no significant changes in any of the anthropometric parameters studied, from admission to discharge. However, the corresponding pairs to the compliant patients from the non-
supplement group (HR-NS-CP) demonstrated a significant loss in both MUAC \( (p < 0.01) \) and MUAMC \( (p < 0.05) \).

Data for the mean group change in serum albumin have not been presented for the four sub groups as there were insufficient values to perform meaningful statistical analyses.

3.6.5 **Indices of clinical outcome**

Table 3.6 represents a summary of the indices of clinical outcome (time to frame mobilisation, duration of hospital stay and location of discharge) of the supplement and non-supplement groups. Although the mean duration of stay in hospital was shorter for the supplement group than the non-supplement group and their time to frame mobilisation was less, these results did not reach statistical significance. There was also no difference in location of discharge between the two groups.

There were no significant differences between the two groups for any of the parameters measured.
Table 3.6

Summary of clinical outcome in the Supplement and Non-Supplement groups.

<table>
<thead>
<tr>
<th></th>
<th>High Risk Supplement (n=18)</th>
<th>High Risk Non-supplement (n=18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to frame mobilisation (days)</td>
<td>6.1 ± 4.2</td>
<td>7.0 ± 6.5</td>
</tr>
<tr>
<td>Duration of hospital stay (days)</td>
<td>20.2 ± 9.8</td>
<td>23.9 ± 15.6</td>
</tr>
<tr>
<td>Discharge location (n)</td>
<td>Home (indep'ent) = 5</td>
<td>Home (indep'ent) = 6</td>
</tr>
<tr>
<td></td>
<td>With relatives = 3</td>
<td>With relatives = 1</td>
</tr>
<tr>
<td></td>
<td>Nursing home = 3</td>
<td>Nursing home = 4</td>
</tr>
<tr>
<td></td>
<td>Conval'ence Hosp = 7</td>
<td>Conval'ence Hosp = 6</td>
</tr>
<tr>
<td></td>
<td>Unknown = 1</td>
<td></td>
</tr>
</tbody>
</table>

Results are presented as mean values ± sd for time to frame mobilisation and duration of stay in hospital.

3.6.6 Nutritional value of the supplements consumed

Seven (39%) of the 18 patients who were offered the supplements either refused to take them on their first offer, or consumed only minimal amounts (20 - 100 mls) in the first few days and then subsequently refused further offers. (For the purpose of statistical analysis, these patients were regarded as being non-compliant, S-NC). In the 11 patients (61%) who did consume the supplement, and were therefore categorised as S-C, the average intake
was 1.6 cans (400 mls) per day. This volume is equivalent to 400 kilocalories and 14.1 grammes of protein per day.
3.7 DISCUSSION

A retrospective review of patients recruited into the feasibility study revealed that between 2 and 3 patients per week admitted to two orthopaedic wards of the RSCH were eligible for recruitment into the study. Approximately 64% of these were regarded as HR, half of whom were allocated into the group to receive sip feed supplements. Of those who were asked to consume the supplement, approximately 61% complied to the request. Thus, from these figures it was possible to forecast that if recruitment continued at the same rate, approximately 1 patient every 2-3 weeks could be expected to be recruited into a supplement group and comply to the regimen (2 - 3 patients per week x 64% HR x 50% alternate allocation x 61% compliance). However, when planning a similar but larger long-term trial, there are several additional factors to consider which could reduce the anticipated recruitment rate. One such factor was the seasonal variation in proportion of emergency and elective admissions. The patients discussed here were recruited into the study between December and May, encompassing a large proportion of the Winter months when the incidence of admissions for emergency surgery due to fractured femur is the highest (Bastow et al., 1983b). As the emergency admissions accounted for approximately 80% of the HR patients in this feasibility study, recruitment during the months when the percentage of admissions for elective surgery is higher would be expected to yield a lower number of HR patients. Other factors which are likely to influence recruitment will be discussed later.

There were no significant differences in the admission characteristics or the admission measurements between the two groups of patients allocated into the supplement and non-supplement groups. This indicates that they were from the same population.
The non-supplemented group showed a significant decline in both MUAC and MUAMC from admission to discharge. This indicated that the patients suffered a deterioration of body muscle stores during their period of hospitalisation. In contrast, the group of patients receiving the supplements demonstrated no such decline over the same period of study, suggesting that provision of nutritional supplements on a daily basis, in addition to normal foods, can prevent the depletion of body protein stores which may otherwise occur in such patients over a three-week period of hospitalisation. Unfortunately no subsequent assessment of body weight was possible and therefore changes in total body weight cannot be commented upon.

These results contrast slightly with the work of Banerjee et al. (1978), in which the provision of a supplement (265 kilocalories and 18.6 grammes of protein) over a 14-week study period resulted in an improved triceps skinfold thickness ($p < 0.001$) in long-stay elderly patients. However, this study period was much longer and, as the authors give no indication of the level of improvement over time, it is not possible to compare the results directly. In another study involving long-term geriatric patients (Elmståhl and Steen, 1987), 8 weeks of nutritional supplementation with 500 kilocalories resulted in no significant changes in bodyweight, MUAC, TSF or subcapular skinfold thickness.

A more appropriate study group for comparison may be that of McEvoy and James (1982), who studied the effect of four weeks’ supplementation (644 kilocalories and 36.4 grammes of protein) in patients admitted to an acute geriatric ward. In the treatment group, there was a significant gain in weight ($p < 0.001$), TSF ($p < 0.001$), and MUAC ($p < 0.05$) compared with the control group. There was also an increase in MUAMC although this did not reach statistical significance ($p > 0.1$). Their results suggested that the
observed weight gain in the treatment group was largely due to an increase in fat rather than in protein. Again, the authors gave no indication of the timescale of change and, as the level of supplementation was much higher in this group of patients, it would be anticipated that any changes should have been observed at an earlier stage. Thus, again, a direct comparison cannot be drawn.

One study which did use the same population group and studied patients for a similar length of time was that of Bastow et al. (1983a). However, again, a direct comparison cannot be made as the level of supplementation was much higher (1000 kilocalories and 28 grammes of protein), and was administered by overnight supplementary naso-gastric tube feeding. On admission, these patients had been categorised into three groups; well-nourished (Group 1), thin (Group 2) and very thin (Group 3). The provision of the naso-gastric feed led to an increase in the anthropometric measurements in the group classified as thin, but only the improvement in MUAC reached statistical significance. More striking and significant improvements occurred in the very thin group. As already mentioned, the level of supplementation was much higher and therefore results cannot be compared directly, but the study does raise the important point that the level of response to nutritional support may be dependent upon the degree of deficiency initially.

The results of the present study suggest that the provision of nutritional supplements on a daily basis, in addition to normal food, did prevent the depletion of body reserves which may have otherwise occurred in such patients over the three-week period of hospitalisation. However, the interpretation of the relevance of these findings is limited by the short period of study. To ascertain whether such deterioration in nutritional status is detrimental to long-term outcome, and whether the period of
supplementation conveys any lasting benefit, the need to study patients for a much longer period is reinforced. Over a longer period, changes in overall bodyweight as well as changes in body fat and muscle reserves can be assessed.

The decline in muscle protein indicated by the decline in MUAMC was not reflected in the plasma albumin concentrations which demonstrated no significant change from admission to discharge in either group. It was not possible to obtain blood samples from all the patients and the lack of significant findings may partially reflect the small number of samples. However, plasma albumin has a half-life of approximately 20 days and may therefore not be expected to reflect any change in protein status over a three-week study period.

In the study of Banerjee et al. (1978), even after 14 weeks of supplementation, no significant difference was seen in the albumin levels between the control and the supplemented groups. No difference was also seen in the plasma proteins with a shorter half-life, globulin and transferrin.

In the study of McEvoy and James (1982), after four weeks of treatment with a nutritional supplement, there was a slight increase in serum albumin but the results were not statistically significant. The same can be said of the community study of Lipschitz et al. (1985), although the positive increment in serum albumin was significant in one patient (p <0.001). The mean values of serum albumin in the study of Harrill et al. (1981) were identical before and after supplementation, although 22% of the patients were regarded as having a low serum albumin before supplementation which decreased to 17% after supplementation.
The mean concentration of the shorter half-life protein plasma pre-albumin was also not significantly improved in the 8-week study of Elmstahl and Steen (1987). Even the relatively high degree of supplementation achieved in the naso-gastric feeding study of Bastow et al. (1983a) showed no significant difference in serum albumin concentration between Groups 1 and 2. This value however was significantly lower on admission in Group 3 than in Group 1, and the rise to normal after operation was much slower.

The results from all these studies suggest that albumin is a rather insensitive indicator of protein status and that even the shorter half-life proteins such as pre-albumin, globulin or transferrin may not be sensitive enough to be used as an indicator of short-term changes in protein status. Determination of plasma retinol binding protein (RPB) with a half-life of approximately two days could be employed as a sensitive indicator of short-term protein status. It is however important to assess not only short-term changes but also to evaluate any long-term effects, and the determination of plasma albumin concentration over a long time period would provide a useful index of any long-term changes in protein status.

The use of muscle function tests as tools of nutritional assessment can be criticised for the lack of specificity (discussed in Chapter 2) and in particular the use of voluntary hand grip strength measurements in a group of subjects who may be suffering from arthritis is of questionable validity. Voluntary hand grip strength is a very subjective assessment and it is likely that the results reflect changes in several factors. The influence of other factors will be discussed later (Chapter 4).

There were no notable differences in the indices employed as measures of clinical outcome. However, these were relatively crude and insensitive and influenced by many non-nutritional factors. Such low levels of nutritional
supplementation may require a much longer period of evaluation before any differences in clinical outcome become apparent. Extending the period of study would therefore enable more subtle parameters of clinical assessment to be evaluated.

Poor compliance to the sip feed supplement cannot be ignored as this was a problem for 39% of the supplemented group. In the sub-group regarded as being compliant to the regimen, a large proportion of these patients consumed an average of less than 1 can per day and no patient consumed more than 2 cans per day. This is significantly less than the volume which they were asked to consume of 2 to 3 cans per day. The rate of compliance may be improved by offering a wider choice of flavours, textures and mouth feel. Although there were no significant differences in admission characteristics of the non-compliant group, it may be possible to identify certain other characteristics attributed to the non-compliant patients in a larger study population. It would also be valuable to note the reasons for non-compliance in such a group.

The problem of poor compliance poses a dilemma in the analysis of the results - whether to use the intention-to-treat approach and analyze the whole supplement group, or to assess the true benefit of supplement by analysing only the group who complied to the regimen. It could be argued that this problem could be overcome by the use of a placebo; however, to give a placebo to a group of potentially nutritionally-at-risk patients was considered unethical as well as being almost impossible to manufacture.
3.8 CONCLUSIONS AND FUTURE PLANNING

The data obtained from this feasibility study enabled improvements to be made in the design and planning of the larger study (Chapter 4) and enabled patient numbers, recruitment rates and therefore time plans to be more accurately forecast. It was clear from the feasibility that further studies were required to ascertain the potential long-term benefits of sip feed supplement and this will necessitate extending the period of assessment into the post-discharge period.

It was also clear that the period of supplementation should be extended into the early weeks of convalescence in addition to the hospital stay. This extension phase would impose several limitations upon recruitment rates. Firstly, follow-up of patients into the convalescence period would mean that less time was available for the investigator to recruit and study patients whilst in hospital. Secondly, the collation of such large amounts of data involved in a large-scale study would mean that it was necessary for the investigator to carry out the patient recruitment on a periodic basis. Thirdly, it is possible that some patients would refuse home follow-up, which must be allowed for in the recruitment plan.

All of the above factors considered, it was estimated that within a recruitment period of approximately 18 months, a total of approximately 130 patients (56 patients every six months x 14 months' recruitment) could be recruited into the study. This would result in approximately 65 patients being categorised as HR in whom 32 to 33 would be allocated to receive the supplement and, of these, approximately 16 to 20 patients would be estimated to comply to the regimen (assuming a compliance rate of 50-60%).
With regard to the monitoring assessments, as already stated, it was felt necessary to include a more sensitive indicator of change in protein status; plasma retinol binding protein would provide such a marker.

The mental function test used here was largely aimed at assessing short-term and long-term memory only and it was considered more appropriate to use a test which comprises general cognitive assessment.

The apparatus used to determine voluntary hand grip strength in the study required an electrical power supply and would therefore not be practical for post-discharge assessments. It was decided that a portable apparatus should be used.

In addition to these amendments, two other factors were considered important. Firstly, to assess in detail the factors which affected compliance in this group of patients and secondly to assess the effect of the supplements on normal food intake. Such factors were taken into consideration in the design of the long term follow up study (Chapter 4):
Chapter 4

Sip Feed Intervention and Long Term Follow Up Study
Chapter 4
SIP FEED INTERVENTION AND LONG-TERM FOLLOW-UP STUDY

4.1 INTRODUCTION

As previously highlighted in Chapter 1 (1.1) the proportion of elderly in the general population is increasing and consequently many of the conditions associated with ageing are becoming more prevalent. Two such conditions are osteoporosis, particularly affecting females, and osteoarthritis (Chapter 1.8).

The presence of osteoporosis, coupled with the trauma of a fall, results in a fracture of the hip for many elderly people, requiring surgery for internal fixation and a period of hospitalisation. About one-third of people over the age of 65 years fall, and 2% of all elderly patients receive medical treatment each year as a result of their falls (Cooper, 1987). A recent community-based survey of falls in the elderly found that the prevalence of reported falls rose with ages between 65 to 80 years, but reached a plateau thereafter (Wickham et al., 1989). Falls were reported almost twice as frequently in females as in males at any age.

Osteoarthritis is a common degenerative joint disease with unknown aetiology which affects millions of people. In fact, the Arthritis Foundation claims that every person over the age of 60 years has osteoarthritis in some form. However, only in a few is it severe enough for them to seek professional help (Arthritis Foundation 1985, cited in Selman, 1989). Those suffering from osteoarthritis of the hip often warrant a total joint replacement due to the relentless pain which causes difficulty in walking and sitting. Although all joints can be replaced, total hip replacement (THR) is the most successful. Because the incidence of arthritis increases with advancing age, and females generally survive longer than males, the
procedure is performed more frequently in women than in men. For these reasons, elderly female patients occupy an increasing proportion of orthopaedic bed space, whilst undergoing surgery for either repair of a fractured neck of femur or for a total hip replacement.

A review of the literature reveals that the outcome of patients with femoral fractures is not good. As discussed in Chapter 1 (1.8), several studies have reported high mortality rates following hip fractures, particularly in the weeks immediately following surgery. Although the precise mortality rates differ in terms of actual percentage, and times of peak, the magnitude and trends are similar. Mortality rates during hospitalisation were calculated to be in the order of 10%, ranging from 8.3% (Miller, 1978) to 13.9% (Dahl, 1980); and one-year mortality figures were found to be 27% (Miller, 1978; Steen Jensen and Tøndeved, 1979). Mortality has been reported to be the greatest within the first 12 weeks after fracture (Gordon, 1971) and the first two months (Dahl, 1980). In this latter study of 675 patients, the mortality during the first month was about 15 times and during the second month about 7 times the expected mortality of an age- and sex-matched Norwegian population.

Mortality is an important statistic but perhaps more important is the prognosis for the survivors. Following hip fracture, social function has been shown to deteriorate following discharge from hospital (Steen Jensen and Bagger, 1982). It could be argued that patients who are more independent have a better quality of life and this is something to be aimed for.

The impact of THR on quality of life for those persons who have suffered osteoarthritis of the hip has been described in a detailed study of 46 subjects and evaluated by the participant's perception of change in four areas (Selman, 1989). The four areas were physiologic functioning, self-
concept, role function and inter-dependence. All areas showed a positive change and overall satisfaction with THR. However, if the results are examined more closely, 54% patients reported either a negative change, or no change in inter-dependence, 24% in self-concept and 17% in role function. It is notable that in the area of inter-dependence, a high percentage of the patients perceive there to be a marked negative change. Also, with the high technical success rate of a THR, it is easy to forget those patients whose surgery has been unsuccessful and who have then have to endure long waiting lists before a repeat operation can be performed. In these patients nutritional status may have deteriorated as a direct result of the first operation and not recovered by the time the operation is repeated. Similarly, as a consequence of repeated falls, patients requiring a further surgical procedure for the repair of a hip fracture, may enter a downward spiral of decreasing nutritional status.

As discussed in Chapter 1 (1.5), the mobility and social isolation which are frequently associated with the elderly can have deleterious effects on accessibility to food, food intake and nutritional status. Therefore it can be clearly appreciated that elderly patients admitted to hospital for orthopaedic surgery are more likely than some other groups to be suffering some degree of nutritional depletion at the time of admission. There is also evidence that this group have notably impaired nutrient intakes in the early post-operative period (Chapter 1.9). This deficit between requirement and intake is likely to further compromise the nutritional status of these patients and the increased metabolic demands of orthopaedic surgery seem unlikely to be met.

Nitrogen balance studies, undertaken in elderly women (mean age 81 years) following surgical repair of femoral neck fractures, have quantified the difference in the intake and expenditure of 61 patients (Stableforth, 1986).
The intake of ward food was found to vary widely, but was always low, the mean daily intake being 127 mg N/kg body weight (mean daily intake of protein 31 g) and 17 kcal/kg. Daily nitrogen production was 85-250 mg N/kg (mean 158 mg N/kg) and calorie expenditure was 17-48 kcal/kg daily. In this 10 day study, 90% of the patients were in negative nitrogen balance and 100% were in negative energy balance (details presented in Chapter 1.9). In an attempt to increase nutrient intake, all patients had been encouraged to consume a sip feed supplement containing 18.5 g protein and 320 kcal, however, poor tolerance to the supplement prevented these deficits being corrected. It is important to note that the method used to estimate daily energy expenditure in this study made no allowance for the increased energy expenditure of trauma and, therefore, energy deficit was almost certainly higher than the results imply. From these data, the author concluded that a daily energy intake of 175 kcal/kg and a nitrogen intake of 175-200 mg N/kg would be required to achieve a zero balance. In the group receiving ward diet alone the mean intakes were 17.7 ± 7 kcal/kg (887 ± 350 kcal/day) and 96.5 ± 27 mg N/kg (27.0 ± 11 g protein/day) with the corresponding intakes of the supplemented group being 129.4 ± 25 mg N/kg (40.4 ± 11 g protein/day) and 19.1 ± 5 kcal/kg (1075 ± 190 kcal/day). This study clearly highlights two points: firstly, the high nutritional requirements of elderly women with a fractured femoral neck are not during the initial post trauma period, and secondly, that compliance to sip feed supplements is poor in this group. Such insufficient nutrition can lead to catabolism of serum and muscle protein, resulting in less protein for the protein synthesis of new tissue and less strength for breathing and movement; impairment of the immune system by altering antibody response time; increased susceptibility to common complications such as pulmonary stasis, bronchopneumonia; and possible hypoalbuminaemia and intestinal oedema which retards cellular exchange of nutrients and
decreases skin elasticity making it more susceptible to injury and the development of decubitus (pressure sores).

Body composition prior to injury, the labile protein pool and glycogen store will all affect the degree of post traumatic loss of nitrogen and therefore are likely to influence the course of recovery. Following the trauma of fracture and/or surgery, blood levels of cortisol, glucagon, catecholamines and growth hormone tend to be elevated. In general, the increases are in proportion to the magnitude of injury and plasma concentrations return toward normal as wound healing occurs and convalescence progresses. This metabolic response to trauma is mediated by the neuroendocrine axis, and differences in body composition appear to have little effect on the endocrine response of the host. The adrenocortical response to surgical stress in malnourished patients has been shown to be similar to that of normally nourished patients (Moore, 1959) and similarly, the response to surgical stress does not appear to be altered with advancing age (Stoner, 1977). Post-traumatic plasma cortisol levels have been correlated with severity of injury (Stoner, 1977). Other workers have also noted that the endocrine and metabolic responses to minor elective surgery are similar in elderly and young adult males, with the exception that higher cortisol levels were observed in the older men (Blichtert-Toft et al., 1979). Although the endocrine response appears to be relatively unaffected by the nutritional status of the host, the ability of the host to meet the metabolic demands for nutrient substrates must be influenced by the nutritional status of the patient. The role of these circulating hormones will be discussed more fully in Chapter 6 (Discussion).

As well as changes in circulating hormone levels, there is an induction of inflammatory mediators, cytokines, which initiate release of acute phase proteins. Interleukin-1 (Endogenous Pyrogen) is a peptide, or closely
related group of peptides, that may serve as a mediator of acute phase changes following injury and sepsis. Little is known about Interleukin-1, but it is thought to be synthesized by tissue macrophages such as hepatic Kupffer cells and splenic and pulmonary macrophages, and blood monocytes. In the case of trauma resulting from a fracture the inflammatory response in the macrophages has already been provoked and the acute phase response will already have been initiated by the time the patient reaches hospital. In the case of elective surgery, this response will be initiated following surgery.

The increased metabolic requirements of patients sustaining orthopaedic trauma or undergoing orthopaedic surgery, or both, are often overlooked. Fracture, major surgery and infection all induce a hypermetabolic state. Adequate supplementation with exogenous nutrient substrate is essential to protect the patient from excessive net protein catabolism and to meet the increased energy requirement. Endogenous glycogen stores in the liver and the skeletal muscle are minimal (about 300 g, 1200 kcal), and can be depleted within 12 hours. Preferential sparing of protein by body fat stores may not be possible because in severe metabolic stress, fat is a relatively unavailable energy substrate. The utilisation of protein for energy results in the loss of visceral and skeletal muscle mass and compromises body function. Protein depletion has been repeatedly correlated with increased mortality, increased surgical failure, impaired wound healing, increased wound infection, sepsis, pneumonia, progressive weakness and apathy, and delayed physical rehabilitation. Such complications not only prolong the course of recovery for the patient but also increase medical costs, in terms of time and treatment. Thus, the nutritional status of an individual prior to trauma can influence the long term clinical outcome as the host attempts to meet the increased metabolic demands.
A study of 129 patients undergoing orthopaedic surgical procedures has provided some important information regarding the incidence of nutritional depletion in the orthopaedic patient population on admission to hospital and the development of subsequent complications (Jensen et al., 1982). Two groups of patients were studied; Group 1 consisted of 74 patients undergoing major elective orthopaedic surgery (including a sub-group of 36 THR patients); and Group 2 consisted of 55 patients with multiple trauma and major long-bone fractures (including a sub-group of 38 patients with femoral fracture) who had surgery. Of the patients who developed complications, 59% had at least one severely-abnormal initial evaluation of visceral proteins (as indicated by serum transferrin < 150 mg/dl, serum albumin < 3.0 g/dl, total lymphocyte count < 1000 cells per mm³ or allergy to skin antigen testing 0mm of induration). Baseline nutritional data (including nutritional intake, nitrogen balance and anthropometry) were collected at two days pre-operatively for Group 1 (elective surgery), then at two, seven and seventeen days post operatively in order to assess the effect of surgery. The same data were collected for the patients in Group 2 (trauma), at 5 days after injury. In both groups all nutritional assessments were repeated every 10 days thereafter until the patient was regarded as nutritionally normal, or until discharge. The effect of total hip replacement surgery was monitored by the repeated measurements. The anthropometric measurements (TSF and MUAMC) had not changed significantly two days after surgery, but had declined significantly by the seventeenth post-operative day. The protein and calorie intakes were both decreased on the second day, but had usually returned to "normal" by the seventeenth day. The average daily nitrogen balance followed a similar pattern with significant reduction early in the post-operative period. However some patients were still in negative nitrogen balance by days seven and seventeen. Concentrations of serum albumin and transferrin were also significantly reduced on the second post-operative day but had returned to
normal by the seventeenth day. These results demonstrate the effect that THR surgery has on reducing both somatic and visceral protein stores in the immediate post-operative period. The clinical consequences of this decline in protein status were demonstrated by the observation that, during hospitalisation, twelve complications occurred in nine THR patients and the best single pre-operative predictor of complications appeared to be mid arm circumference. Similar observations were reported in the measurements of nutritional indices in the group with multiple trauma, who showed a depressed arm muscle circumference, creatinine height index, serum transferrin and the development of a negative nitrogen balance. All of these observations were significantly correlated with infectious complications, again high-lighting the importance of nutritional status in relation to clinical outcome.

A high incidence of protein calorie malnutrition has also been reported in a study designed to make a prospective assessment of nutritional status of forty consecutive patients admitted to hospital with hip fractures, and then relate these findings to long term complications (Foster et al., 1990). The nutritional parameters measured included serum albumin, serum transferrin, anthropometric measurements (TSF, MUAC), skin testing for delayed hypersensitivity, total lymphocyte count and a 24-hour urine collection for metabolic and nitrogen balance determinations. Of the nutritional parameters studied, serum albumin was the strongest predictor of mortality (p < 0.004). In those patients with an albumin of < 3.0 g/l on admission the observed mortality was 70% in the follow-up period of 11 months, compared with 18% in patients with an albumin of ≥ 3.0 g/l. These results again emphasise the importance of protein status on clinical outcome. The authors concluding remarks were that hip fracture patients should have nutritional intervention during hospitalisation, based upon their serum albumin on admission, and that a long term follow up of 6-12
months should be a sufficient period of evaluation. As they also pointed out, "The more crucial question is whether or not the pre-morbid levels of ambulation and independence (essentially restoration of the quality of life) of the elderly affected with hip fracture can be restored more consistently with nutritional intervention".

A more recent, prospective study has been performed to determine the effect of protein depletion and post-operative nutritional state on the outcome of 63 elderly (> 50 years) patients who had been admitted to hospital because of a fracture of the hip (Patterson et al., 1992). Enteral supplements in the form of a canned high-calorie high-protein liquid (commercial name not stated) were provided for all patients post-operatively. Although no mention was made of the amount of supplement that the patients consumed, total daily intake of protein and calories, including the supplement, were reported. Despite supplementation, the average net nitrogen deficit on the 4th post-operative day was 44mgN/kg/bw (range -215 to +49 mgN/kg/bw). By the 8th post-operative day, the average deficit had decreased to 16 mgN/kg/bw (range -105 to +104 mgN/kg/bw). After 11 days, there was an average positive value of 30 mgN/kg/bw (range -80 to +140 mgN/kg/bw) and all patients had returned to a positive nitrogen balance ten days after the operation. This study showed that, despite nutritional supplementation, these patients remained in a catabolic state in the early post-operative period. Measurements of levels of visceral protein (albumin, prealbumin and transferrin) were all low on admission for the entire group and the changes observed over the post-operative period were similar for all three parameters. There was a general improvement over time in those patients who did not develop complications, but no improvement was seen in the group of 11 patients who did develop complications. Thirty-eight (90%) of the 42 patients who returned for their four week follow-up evaluation had a complete recovery of the stores of
visceral protein to normal, or above normal, levels. However, it could be argued that the patients who did not return for their follow-up evaluation, may be those who were in a poorer state of recovery and the protein status of these patients may be below normal. Differences in clinical outcome were observed between the patients who were considered to be protein-depleted and those who were considered to have a normal protein status. The average duration of stay in hospital was 19 days (range 8 to 90 days); 37 protein-depleted patients were hospitalised for a mean of 21 days and the 26 non-protein-depleted patients for a mean of 15 days. Although these differences were not statistically significant, due to the wide range in both groups (not reported), the results suggest that nutritional status may be an important determinant of the clinical outcome and thereby the duration of stay. Despite the provision of nutritional supplements, during hospitalisation, 8 patients (13%) were considered to be normo-caloric (food intake of kilocalories equal to or exceeding those of the estimated requirement for basal metabolism), whereas 55 patients (87%) did not ingest an adequate amount of protein and calories during the post-operative period. When the basal metabolic requirement was adjusted by a factor of 25%, as has been suggested for patients who have an isolated fracture of the long bone, none of the patients were able to ingest sufficient calories to meet basal requirements. These results alone indicate the potential for a more intensive supplementary feeding regimen. Mortality in the 12 month period after surgery was 24%, similar to that reported by other workers, three of these patients dying before discharge from hospital. Thirteen of the 60 patients who did not die in hospital could not return to their pre-fracture environment and of those who did, many required additional resources to cope with the tasks of every day living. Although many factors contributed to the ability of the patient to return home, the prevalence of severe protein depletion was two-fold higher in the patients who were unable to return to their pre-fracture environment. There is a clear need to investigate
whether correcting this protein depletion, by the provision of nutritional support, could improve the rehabilitation of these patients.

Not only is the cost of a stay in hospital greatly increased for malnourished patients compared with those who have good nutrition (US $ 6,500 compared with US $ 1,750 respectively) according to a study of 771 patients (Reilly et al., 1988), but they are also more likely to expend more healthcare resources after discharge. This study of 63 hip fracture patients suggested that 30 kcal/kg bw/day and 1.5 grammes of protein/kg bw/day would have been sufficient to offset the increased metabolic demands of trauma. If patients could be encouraged to voluntarily consume nutritional supplements, these could provide a large proportion of their requirements and probably improve outcome, not only whilst in hospital but also following discharge from hospital.

The results of the feasibility study (described in Chapter 3) showed that the impact of nutritional support could only be partly evaluated when patients were followed up during their period of hospitalisation. It was concluded that to ascertain the full effects of supplemental feeds, it would be necessary to continue to study these patients into the discharge period. It is clear from the results of studies previously described (Jensen et al., 1982; Foster et al., 1990; Patterson et al., 1992), that patients undergoing orthopaedic surgery remain catabolic for at least one week following the surgical procedure and during this time, the utilisation of nutrients is impaired. Thus any study which attempts to evaluate the benefits of nutritional supplementation should include a sufficiently long period of supplementation beyond the catabolic period. As mortality and the risk of complications seem to be greatest in the initial few months following surgery, provision of nutritional supplements for four weeks into the post-discharge period and extension of the follow-up assessments to six months
after discharge from the acute hospital, were considered appropriate for the current study.

Refinements to the original protocol included the addition of the measurement of retinol binding protein, a short half-life protein, and a more general assessment of cognitive functioning. Practicalities dictated that the functional assessment of hand-grip strength required the use of a portable apparatus.

Two important factors which are frequently overlooked in the studies of nutritional supplementation currently reported in the literature, are those of poor compliance to the supplement and the impact of supplements on normal food intake. These are clearly fundamental considerations if the interpretation of the results is to be maximised. The experience of the feasibility study clearly showed that poor compliance is a potential problem and should be taken into account when designing any study, particularly one which involves the voluntary ingestion of nutritional supplements. The second important consideration is that of the impact that consuming the supplements has on the intake of normal foods, the emphasis being on the "supplement" as opposed to "substitution". Both of these factors were taken into consideration when designing the long-term follow-up study, details of which will be presented in the next section of this chapter.

The general aims of the long-term follow-up study could be described as follows:-

1. To provide nutritional support (in the form of voluntary ingested sip feed supplements) to a group of patients who are considered "nutritionally vulnerable", throughout the period when the incidence of morbidity and mortality is known to be greatest.
2. To evaluate the impact of this nutritional support on both short-term and long-term indices of nutritional status, functional assessments and clinical outcome.

3. To monitor compliance to the regimen and to try and identify any characteristics particular to the non-compliant sub-group.

4. To evaluate the effect of providing nutritional support on the nutrient intake from normal foods.
4.2 PATIENTS, EXPERIMENTAL DESIGN AND PROCEDURES

At the end of the Feasibility study (Chapter 3) an audit was performed of all patients who had been admitted to the accident and emergency department of the RSCH from June 1986 until May 1987 (Figure 4.1). During this 12 month period, a total of 167 female and 40 male patients had been admitted to the hospital with a fractured femur. These figures confirmed the higher incidence of fractures in females and thus supported the use of females as a population for study. Over the period of recruitment into the Feasibility study (Chapter 3) a total of 81 female patients with a fractured femur had been reviewed at the Accident and Emergency Department, yet only 29 were recruited into the Feasibility study. The reasons for the differences in numbers can be explained by a large proportion of patients not fulfilling the entry criteria of the study and a small proportion not being available for interview within 72 hours of admission. Nevertheless, it was anticipated that the emergency and elective admissions combined would provide an appropriate number of patients for a long term evaluation study.

The study described in this chapter was performed on the two orthopaedic wards of the Royal Surrey County Hospital (RSCH) Guildford, on patients who were admitted on weekdays between January 1988 and June 1989. Ethical approval for the study was granted from the Hospital Ethics Committee. Informed verbal consent was obtained from all patients before participating.
Figure 4.1  Number of male and female patients admitted to the accident and emergency department of the RSCH with a fractured femur between June 1986 and May 1987.
4.2.1 Patients

4.2.1.1 Inclusion criteria

1. Female patients

2. Aged 60 years or over

3. Admitted for orthopaedic hip surgery, either as an emergency case (fractured femur) or as a planned elective admission (hip replacement).

4.2.1.2 Exclusion criteria

1. Patients with mental impairment, with whom reliable and effective communication was not possible (for example, long-standing senile dementia or temporary post-operative confusion).

2. Patients who would be discharged to another hospital immediately after surgery (for example, private patients spending their post-operative period of hospitalisation in a hospital other than the RSCH).

3. Patients in whom, for practical reasons, follow-up visits into the post-hospital discharge period would not be possible (for example, those patients who would be discharged to a place outside a 30 mile radius of Guildford).

4. Patients who refused consent to participate.
4.2.2 Experimental design
The Investigator visited the hospital each weekday morning and reviewed the hospital case notes of newly-admitted patients. Each potentially-eligible patient was approached within 72 hours of admission (usually 24 hours) when a brief introduction and explanation of the study was given. The aims and procedures involved, and the duration of the study, were all explained to the patient and any questions were answered. They were also informed that they were free to withdraw from the study at any time without prejudicing their future care in any way. Those patients agreeing to participate underwent a structured interview during which time, responses to a nutrition risk questionnaire (NRQ) were completed to provide a nutrition risk score (NRS) for each patient. (The use of this questionnaire has been discussed in Chapter 2, Methodology, and a copy can be found in Appendix II.) Any patient with a NRS of < 8 was considered to be "low risk" (LR) and was not studied further within the framework of this protocol. Those patients receiving a NRS of ≥ 8 were categorised as "high risk" (HR) and provided the study population for the evaluation of the effect of sip feed supplements on nutritional and clinical outcome.

On each of the two wards, the patients categorised as HR were alternately allocated to either the group who were offered nutritional supplements, termed the "supplement group" (S) or to the group who were not offered the nutritional supplements, the "non-supplement group" (NS). Both study groups underwent the same assessment procedures, the NS group serving as the control for the S group.

Poor compliance in the S group was recognised as a potential problem and this method of alternate allocation was chosen because it enabled retrospective pairing of patients who complied to the regimen, with their corresponding "admission pairs" from the NS group. The subjects in the S
group were asked to consume the equivalent of approximately 500 kcal and 20 g protein from a choice of supplements, on a daily basis, for the duration of stay in hospital and for four weeks into the post-discharge period. For the purpose of categorising patients into compliant and non-compliant sub-groups, compliance was defined as the consumption of at least 250 kcal per day for at least 75% of the time requested. The choice of supplements offered was Fortimel: (Cow and Gate), Protipudding (Cow and Gate) and Liquisorb (E. Merck). The nutritional composition of these supplements is given in Appendix IV, Tables A4.1.

All patients were visited each weekday whilst in hospital and at two weeks, four weeks, eight weeks and six months after discharge from the RSCH.

4.2.3 Procedures and assessments

Further details of assessments are described in Chapter 2, Methodology. A summary of the procedures and assessments is given in Table 4.1.

4.2.3.1 Background information

Patient identification, demographic data, a brief social and medical history and details of the surgical procedure and type of prosthesis were recorded for each patient.
## Table 4.1
Summary of procedures and assessments

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Admission / hospital</th>
<th>Discharge</th>
<th>Time post-discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1-2 weeks (Check up visit only)</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Body weight</td>
<td>(X)</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>TSF</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>MAUC</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>ALB</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>RBP</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>vHGS</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>CAPE</td>
<td>(X)</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>VISICK</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>24 hour dietary recall</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>
4.2.3.2 Anthropometric assessments
Baseline anthropometric measurements were taken on admission and at weekly intervals during hospitalisation, until discharge, then at two weeks, four weeks, eight weeks and six months post-discharge. The measurements taken were; triceps skinfold thickness (TSF) and mid upper arm circumference (MUAC), from which mid upper arm muscle circumference (MUAMC) was derived using the formula described in Chapter 2. Due to pain (osteo arthritis) or immobility (traction) it was not usually possible to obtain an admission assessment of body weight for most of the emergency cases and several of the elective cases. The patient’s recollection of their "usual" body weight was documented and each patient was weighed in the ward "chair-balance" scales just prior to discharge.

4.2.3.3 Biochemical assessments
A sample of blood (5 - 10 mls) was obtained on admission, at discharge and at four weeks and six months into the post-discharge period. All samples (with the exception of the admission sample) were collected by the investigator, centrifuged at 2000 - 3000 rpm and aliquots of serum were stored at -18°C until the time of analysis. Determination of retinol binding protein and serum albumin concentrations were made according to the methods described in Chapter 2. The results of routine hospital blood tests (haemoglobin, white cell count and creatinine) which were taken on admission, were also documented.

4.2.3.4 Functional assessments
Voluntary handgrip strength was assessed using a portable handgrip dynamometer at baseline, then at weekly intervals until discharge. Further assessments were made at two weeks, four weeks, eight weeks and six months into the post-discharge period. Mental function was assessed using the 12 item Information/Orientation Scale from the Clifton Assessment
Procedures for the Elderly (CAPE) (Pattie and Gillett, 1975; Pattie and Gillett, 1977). To allow sufficient time for any carry-over effects of the anaesthetic, dehydration or post-operative confusion to be overcome, the baseline assessment of mental function was not made until approximately one week after surgery, by which time the patients appeared to have stabilised. Further assessments were made at four weeks and six months post-discharge.

4.2.3.5 Dietary assessments
At each daily visit in hospital, the patient was asked to give a subjective assessment of their appetite on that day. In addition to this, a 24-hour dietary recall was performed after one week of hospitalisation, and at four weeks and six months into the post-discharge period. Whilst in hospital, if recollection was difficult, the ward menu cards were used as a prompt to assist patient memory. In a few cases the meal trays were kept to determine how much of the meal provided was actually consumed. In the post discharge period, the dietary recall was based on patient recollection of the previous 24 hours’ food intake (using the standard interview technique) and was frequently confirmed by communication with the patient’s relatives (if living in their care) or the nursing staff (if in a convalescent hospital or nursing home). The calculation of nutrient intake was based on standard hospital portion sizes (obtained from the hospital catering department) whilst in hospital and average household portions (Crawley, 1988) in the post discharge period. The nutrient data were analysed by means of a Compeat software programme (Lifeline Nutritional Services Ltd.).

Patients were asked not to discard any unused supplement, so that an estimation of the amount of supplement consumed could be recorded. If the cartons had been inadvertently discarded, the patient and/or the nursing
staff were asked to estimate the amount consumed. In the post discharge period, a record was kept of the amount delivered and the patients were asked how much they had consumed since the previous visit. In some cases, the patient (or relatives) maintained their own written records which were collected and used in determining the amount consumed.

4.2.3.6 Clinical assessments
Clinical outcome was evaluated by recording times taken to achieve specific objective end points. These were:

- duration of stay in the acute hospital.
- duration of stay in the convalescent hospital.
- place of living and independence of mobility (modified VISICK score) at the subsequent assessment periods following discharge from the acute hospital.
- complication rates (both technical in nature and medical).
- mortality during the period of study.
4.3 **STATISTICAL ANALYSIS AND PRESENTATION OF RESULTS**

The data from many of the parameters measured did not show a normal distribution and therefore non-parametric statistical tests have been used throughout the analysis. Results are presented as median values (with 25th and 75th centiles). Changes within groups, from the baseline value, were assessed by the Wilcoxon matched-pairs signed-ranks test; differences in median values between groups, or differences in changes with time between the groups, were assessed by analysis of variance (Kruskal-Wallis) and their significance tested by Mann-Whitney U Wilcoxon Rank Sum W test. Data was entered into a data file with statistical analysis being performed using the SPSS-PC software for personal computers.

The data have firstly been presented using the "intention to treat analysis", where the results of the S group have been compared with the NS group, irrespective of compliance. In addition, in order to evaluate the impact of the supplement regimen when taken as prescribed, results from the S-C group have been compared with the results of the NS matched admission pairs (NS-CP). In all cases, differences were considered to be statistically significant at the $p < 0.05$ level.

For clarity, the figures have been presented using median values only and the statistically significant changes from baseline to each time point, within the study groups, are shown by asterisk (*). The corresponding data, including the 25th and 75th percentiles have been presented in a table beneath each figure, in which the statistically significant changes between the groups have been indicated.

Some of the results have also been presented as mean values ($\pm$ sd) in order to enable comparisons to be made with data presented by other workers.
4.4 RESULTS

4.4.1 Recruitment and categorisation of patients

Each day, after reviewing the hospital notes and admission summaries of new admissions, potentially suitable patients were approached, informed about the study and asked whether they would be willing to participate. Of those approached, only two refused to participate in the study. No further details were recorded on these patients and they were not contacted again. Although they did not have to specify a reason for not wishing to participate, the investigator was of the impression that one patient feared letting strangers into her house and the other patient thought that her nutritional intake was adequate and would not be prepared to consume the supplements if requested.

Although recruitment spanned an 18-month period, active recruitment only took place intermittently. It was not possible for one Investigator to continuously recruit patients throughout this period due to the peaks in workload arising from the high frequency of home visits in the immediate discharge period. During the 18 months’ recruitment phase, a total of 73 patients underwent detailed structured interviews, after which 42 (57.5%) obtained an NRS ≥ 8 and were therefore categorised as high risk (HR). The alternate allocations into the S (Supplement) and NS (Non Supplement) groups (Section 4.2.2) was adhered to for the first 10 patients. However, after the first five patients had been alternately allocated into the group to be offered the supplements, it became clear that, despite being offered a range of supplements, compliance was poor. Of these first five patients allocated to the supplement group, two took only a few sips and then refused further supplies; one had her supplements taken away by nursing staff due to unstable diabetes mellitus four days after discharge to another hospital; and one expressed reservations about continuing the supplement after discharge from the acute hospital (she subsequently consumed the
supplement for only two days following discharge). At this time, a decision was taken to deviate from the systematic alternate allocation and allocate the next five patients to the Supplement group. After these five patients, the system of alternate allocation was reinstated and continued until the end of the first recruitment period, at which time 10 patients had been allocated to the S group and 5 to the NS group. This imbalance in numbers was corrected during the second phase of recruitment when the allocation was one patient to the S group, followed by two patients into the NS group. At the end of the study, this resulted in 21 patients being offered nutritional supplements, of which 13 (62%) were considered to comply to the regimen, termed the Supplement Compliers (S-C); and 8 (38%) were considered Supplement Non-Compliers (S-NC). Ranking the patients in order of admission date for the S and NS groups enabled each of the S-C patients to be paired with a corresponding admission patient, termed the Non Supplement Compliant Pairs (NS-CP). This pairing allowed statistical comparisons to be made between the following sub-groups:

S vs NS groups (evaluating the effect of the nutritional supplement using the "intention to treat" analysis),

S-C vs NS-CP sub-groups (evaluating the effect of the nutritional supplement in those who actually consumed the supplement, the "per protocol" analysis).

In some cases, data have also been presented for the Supplement Non-Compliant sub group (S-NC) in order to evaluate differences between this group and others and to attempt to identify any particular characteristics of this sub group.
A diagrammatic representation of the recruitment and categorisation of patients is presented in Figure 4.2.
Completion of Nutrition Risk Questionnaire (NRQ)  
\( n = 73 \)

Nutrition Risk Score (NRS)

NRS < 8  
Low Risk (LR)  
\( n = 31 \)

NRS ≥ 8  
High Risk (HR)  
\( n = 42 \)

Alternate Allocation

Non-Supplement (NS)  
\( n = 21 \)

Supplement (S)  
\( n = 21 \)

Retrospective "Pairing"

Non-Supplement Admission Pairs of S-NC sub group (NS-NCP)  
\( n = 8 \)

Non-Supplement Admission Pairs of S-C sub group (NS-CP)  
\( n = 13 \)

Supplement Non-Compliers (S-NC)  
\( n = 8 \)

Supplement Compliers (S-C)  
\( n = 13 \)

Fig 4.2  Recruitment categorisation of patients into the long term follow up study
For clarification of presentation (individual patient data), the patients were retrospectively allocated a Patient Number, after they had been divided into the sub-groups as defined above:

<table>
<thead>
<tr>
<th>Patient numbers</th>
<th>Sub-group</th>
</tr>
</thead>
<tbody>
<tr>
<td>01-13</td>
<td>S-C</td>
</tr>
<tr>
<td>14-21</td>
<td>S-NC</td>
</tr>
<tr>
<td>22-34</td>
<td>NS-CP</td>
</tr>
<tr>
<td>35-42</td>
<td>NS-NCP</td>
</tr>
</tbody>
</table>

A summary of the patient details has been given in Appendix IV.

4.4.2 Admission characteristics

A summary of the following admission characteristics: age, reason for admission (emergency or elective surgery) and nutrition risk score (NRS) of the total group of patients interviewed (n=73); the categories of Low Risk (n=31) and High Risk (n=42), as defined by the NRS; and the sub-division of the HR group into S (n=21) and NS (n=21) groups are presented in Table 4.2. The same characteristics are presented according to the four sub-groups (S-C, NS-CP, S-NC and NS-NCP) in Table 4.3. Results are presented as median values (25th, 75th percentiles) where n refers to the number of patients.

The distribution of the NRS values (Figure 4.3) showed two distinct peaks, corresponding to scores of 5 and 11, with the trough between them corresponding to a score of 7.5. A score of 8 or greater had been used to categorise the patients as HR. The scores of the HR group were significantly higher than those of the LR group (p < 0.01). There were no significant differences between the scores of the S and NS groups, between the S-C and NS-CP sub-groups, or between the S-C and S-NC sub-groups (data not shown).
The HR patients were older than the LR patients (p < 0.01). There were no differences in age between the S and NS groups, but the S-C sub group were younger than any of the other three sub-groups (p < 0.05).

In the HR group there was a higher percentage of admissions for emergency surgery than in the LR group (p < 0.001). The percentage of emergency admissions was the same in the S group as the NS group, although when the S group was divided into compliant and non-compliant patients, the S-C sub group comprised a higher proportion of elective admissions than the S-NC sub group (ns).
Table 4.2

Summary of admission characteristics (age, type of admission and NRS) of the total group of patients interviewed, expressed as the total group; the LR and HR categories; and the HR-S and HR-NS groups.

<table>
<thead>
<tr>
<th>Admission Characteristic</th>
<th>Total group (n=73)</th>
<th>Low Risk (n=31)</th>
<th>High Risk (n=42)</th>
<th>HR-S (n=21)</th>
<th>HR-NS (n=21)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>78 (72, 83)</td>
<td>74 (68, 77.5)</td>
<td>82 (70, 86)</td>
<td>81 (75, 84)</td>
<td>83 (79, 89.5)</td>
</tr>
<tr>
<td>Type of admission</td>
<td>Emer = 53.4% Elec = 46.6%</td>
<td>Emer = 35.5% Elec = 64.5%</td>
<td>Emer = 66.5% Elec = 33.5%</td>
<td>Emer = 66.5% Elec = 33.5%</td>
<td>Emer = 66.5% Elec = 33.5%</td>
</tr>
<tr>
<td>NRS</td>
<td>8.5 (5.5,11.0)</td>
<td>5.5 (5.0, 6.25)</td>
<td>11.0 (9.0, 12.5)</td>
<td>11.0 (8.75, 12.75)</td>
<td>10.5 (9.5, 12.5)</td>
</tr>
</tbody>
</table>

Results for age and NRS are expressed as median values (25th, 75th percentiles). The results for type of admission are expressed as percentages, where Emer is defined as an emergency admission and Elec is defined as an elective admission.

Statistical comparisons with LR: * p<0.05, ** p<0.01, *** p<0.001
Table 4.3

Summary of admission characteristics (age, type of admission and NRS) of the four High Risk sub-groups: S-C, NS-CP, S-NC and NS-NCP.

<table>
<thead>
<tr>
<th>Admission Characteristic</th>
<th>S-C (n=13)</th>
<th>NS-CP (n=13)</th>
<th>S-NC (n=8)</th>
<th>NS-NCP (n=8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>77 (73.5, 82.5)</td>
<td>83 (79, 89.5)</td>
<td>82.5 (81, 69.5)</td>
<td>84.5 (80, 88.5)</td>
</tr>
<tr>
<td>Type of admission</td>
<td>Emer = 54% Emer = 46%</td>
<td>Emer = 61.5% Emer = 38.5%</td>
<td>Emer = 87.5% Emer = 12.5%</td>
<td>Emer = 75% Emer = 25%</td>
</tr>
<tr>
<td>NRS</td>
<td>11.0 (8.5, 12.75)</td>
<td>10.5 (9.5, 12.5)</td>
<td>12.0 (9.5, 12.5)</td>
<td>10.5 (9.5, 12.5)</td>
</tr>
</tbody>
</table>

Results for age and NRS are expressed as median values (25th, 75th percentiles). The results for type of admission are expressed as percentages, where Emer is defined as an emergency admission and Elec is defined as an elective admission.

Statistical comparisons with S-C  *  p<0.05
Figure 4.3 Distribution of NRS for the seventy-three patients interviewed.
4.4.3 Baseline assessments

The results of the routine hospital blood tests (haemoglobin, white cell count, platelets and creatinine) are presented in Table 4.4 for the S and NS groups, and for the S-C and NS-CP sub groups. There were no significant differences between the values of the S and NS groups, nor between the S-C and NS-CP groups for any of the routine hospital blood tests.

The baseline data for the anthropometric (TSF, MUAC, MUAMC and bodyweight), biochemical (albumin and retinol binding protein) and functional (voluntary handgrip strength and CAPE mental score) measurements are presented in Table 4.5. Data have been compared between the S and NS groups and between the S-C and NS-CP sub groups. On admission there were no significant differences between the S and NS groups, in terms of TSF, serum albumin, serum retinol binding protein, voluntary HGS or mental function score. However, the S group had significantly lower values than the NS group for; body weight ($p < 0.01$), MUAC ($p < 0.01$), MUAMC ($p < 0.01$), and independence of mobility (Visick) score ($p < 0.02$). Comparisons between the S-C sub group and their admission pairs (NS-CP) revealed similar differences, the S-C sub group having significantly lower baseline values for body weight ($p < 0.05$), MUAC ($p < 0.02$), MUAMC ($p < 0.01$) and independence of mobility ($p < 0.01$).
Table 4.4

Results of routine hospital blood tests (creatinine, haemoglobin, white cell count and platelet count) on admission, for the S and NS groups, and the S-C and NS-CP sub-groups.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>S (n=21)</th>
<th>NS (n=21)</th>
<th>S-C (n=13)</th>
<th>NS-CP (n=13)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creatinine (umol/l)</td>
<td>74 (40, 87)</td>
<td>86 (34.5, 95.5)</td>
<td>72 (46, 93)</td>
<td>61 (22.5, 94.5)</td>
</tr>
<tr>
<td>Haemoglobin (g/100ml)</td>
<td>12.3 (11.0, 12.9)</td>
<td>12.3 (10.3, 13.1)</td>
<td>12.5 (11.2, 13.8)</td>
<td>12.3 (10.8, 13.1)</td>
</tr>
<tr>
<td>White Cell Count (X 10⁹)</td>
<td>9.7 (6.5, 11.3)</td>
<td>10.2 (7.7, 14.5)</td>
<td>8.4 (6.1, 11.2)</td>
<td>10.1 (7.6, 12.5)</td>
</tr>
<tr>
<td>Platelets (X 10⁹)</td>
<td>263 (277, 380)</td>
<td>274 (213, 343)</td>
<td>371 (219, 396)</td>
<td>256 (195, 310)</td>
</tr>
</tbody>
</table>
### Baseline measurements for the S and NS groups, and the S-C and NS-CP sub groups

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Supplement vs Non-Supplement</th>
<th>Supplement Compliant vs Non-Supplement Compliant Pair</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>S (n = 21)</td>
<td>NS (n = 21)</td>
</tr>
<tr>
<td></td>
<td>NS-C (n = 13)</td>
<td>NS-CP (n = 13)</td>
</tr>
<tr>
<td>Body weight kg</td>
<td>42.6 (40.6, 56.6)</td>
<td>53.8 (48.1, 74.0)</td>
</tr>
<tr>
<td></td>
<td>42.6 (40.6, 54.7)</td>
<td>61.8 (54.1, 88.9)</td>
</tr>
<tr>
<td></td>
<td>(n = 18)</td>
<td>(n = 18)</td>
</tr>
<tr>
<td></td>
<td>10.2 (7.7, 12.1)</td>
<td>11.3 (8.9, 15.7)</td>
</tr>
<tr>
<td></td>
<td>10.2 (8.2, 12.2)</td>
<td>12.9 (8.5, 17.1)</td>
</tr>
<tr>
<td>TSF mm</td>
<td>24.8 (21.3, 27.4)</td>
<td>28.0 (24.4, 30.7)</td>
</tr>
<tr>
<td></td>
<td>26.0 (21.5, 27.4)</td>
<td>28.9 (20.6, 33.7)</td>
</tr>
<tr>
<td></td>
<td>(n = 13)</td>
<td>(n = 13)</td>
</tr>
<tr>
<td>MUAC cm</td>
<td>21.1 (19.2, 24.6)</td>
<td>24.5 (20.8, 27.7)</td>
</tr>
<tr>
<td></td>
<td>21.1 (18.5, 24.3)</td>
<td>26.1 (21.6, 27.7)</td>
</tr>
<tr>
<td>MUAMC cm</td>
<td>20.0 (19.2, 24.6)</td>
<td>23.5 (20.8, 27.7)</td>
</tr>
<tr>
<td>Serum Albumin g/dl</td>
<td>39.0 (35.6, 45.2)</td>
<td>43.0 (39.0, 46.0)</td>
</tr>
<tr>
<td></td>
<td>40.5 (35.0, 46.0)</td>
<td>44.0 (40.0, 51.5)</td>
</tr>
<tr>
<td></td>
<td>(n = 18)</td>
<td>(n = 18)</td>
</tr>
<tr>
<td>Serum RBP mg/dl</td>
<td>37.0 (33.5, 46.3)</td>
<td>47.5 (40.1, 60.0)</td>
</tr>
<tr>
<td></td>
<td>37.0 (32.5, 41.5)</td>
<td>41.0 (38.5, 51.3)</td>
</tr>
<tr>
<td></td>
<td>(n = 18)</td>
<td>(n = 18)</td>
</tr>
<tr>
<td>Voluntary HGS (lb/in²)</td>
<td>1.9 (0.3, 4.0)</td>
<td>2.0 (1.3, 4.0)</td>
</tr>
<tr>
<td></td>
<td>1.9 (1.3, 4.0)</td>
<td>4.0 (1.3, 5.0)</td>
</tr>
<tr>
<td></td>
<td>(n = 18)</td>
<td>(n = 18)</td>
</tr>
<tr>
<td>Mental Function (%)</td>
<td>91.7 (76.8, 100)</td>
<td>91.3 (82.6, 100)</td>
</tr>
<tr>
<td></td>
<td>100 (91.3, 100)</td>
<td>91.3 (91.3, 100)</td>
</tr>
<tr>
<td></td>
<td>(n = 18)</td>
<td>(n = 19)</td>
</tr>
</tbody>
</table>

Results are presented as median values (25<sup>th</sup>, 75<sup>th</sup> percentiles) where n = total group unless otherwise stated.

Statistical comparisons between baseline values of S and NS groups, or between S-C and NS-CP sub-groups:

* $p < 0.05$  ** $p < 0.01$  *** $p < 0.001$
Although the results from the current study have been presented as median values (25th, 75th percentiles), to allow comparison with the feasibility study admission values, the TSF, MAUC, MUAMC, body weight and serum albumin measurements have also been presented as mean values ± standard deviation, in Table 4.6. There were no significant differences between the S and NS group mean values of the feasibility study compared with the S and NS group mean values of the present study respectively, with the exception of the mean TSF of the S group being significantly lower in the present study (p < 0.05).
Table 4.6

Comparisons between baseline measurements for the S and NS groups, for the patients in the feasibility and long term studies.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Feasibility Study</th>
<th></th>
<th></th>
<th>Long term study</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>S (n = 18)</td>
<td>NS (N = 18)</td>
<td></td>
<td>S (n = 21)</td>
<td>NS (n = 21)</td>
<td></td>
</tr>
<tr>
<td>Body weight kg</td>
<td>51.2 (± 12.2)</td>
<td>60.2 (± 20.4)</td>
<td></td>
<td>48.4 (± 11.7)</td>
<td>59.9 (± 13.8)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(n = )</td>
<td>(n = )</td>
<td></td>
<td>(n = )</td>
<td>(n = )</td>
<td></td>
</tr>
<tr>
<td>TSF mm</td>
<td>14.7 (± 4.8)</td>
<td>12.8 (± 6.1)</td>
<td></td>
<td>10.3 (± 3.4)</td>
<td>12.6 (± 5.1)</td>
<td></td>
</tr>
<tr>
<td>MUAC cm</td>
<td>26.8 (± 3.8)</td>
<td>27.5 (± 4.8)</td>
<td></td>
<td>25.0 (± 3.6)</td>
<td>28.8 (± 4.9)</td>
<td></td>
</tr>
<tr>
<td>MUAMC cm</td>
<td>22.3 (± 2.8)</td>
<td>23.2 (± 1.9)</td>
<td></td>
<td>21.8 (± 2.9)</td>
<td>24.6 (± 4.0)</td>
<td></td>
</tr>
<tr>
<td>Serum Albumin g/l</td>
<td>37.6 (± 5.6)</td>
<td>38.4 (± 8.3)</td>
<td></td>
<td>40.2 (± 6.4)</td>
<td>42.6 (± 6.3)</td>
<td></td>
</tr>
</tbody>
</table>

Results are presented as mean values ± sd, where n = total group unless otherwise stated.

* p < 0.05 compared with the S group of the Feasibility Study.
In each of the following sections 4.4.4 to 4.4.8.2 data has been presented as absolute median values in figures and median, 25\textsuperscript{th} and 75\textsuperscript{th} percentile values in tables. Statistical comparisons are based on calculations of 1) changes with time, within the groups, with statistical significant changes indicated on figures and, 2) differences in changes with time, between groups, with statistically significant differences indicated in tables.

4.4.4 Changes in anthropometric measurements from baseline (admission/hospital) to 6 months post-discharge

Anthropometric measurements (bodyweight, TSF, MUAC, MUAMC) from baseline (initial assessment) to six months post-discharge are presented in Figures 4.4a to 4.7a, for the two study groups (S and NS) and Figures 4.4b to 4.7b, for the sub-groups (S-C and NS-CP). The numerical data are also presented beneath the figures in Tables 4.7a to 4.10a (S and NS) and Tables 4.7b to 4.10b (S-C and NS-CP).
4.4.4.1 Bodyweight
(Figures 4.4a and 4.4b, Tables 4.7a and 4.7b)
In the group who were not offered the nutritional supplements (NS), a significant decline of -5.3 kg was observed in body weight from the baseline value to the end of the period of supplementation, four weeks after discharge (p < 0.01). In contrast, the group who were offered the nutritional supplements (S) demonstrated an increase in body weight of +1.1 kg over the same period, although this was not statistically significant. Throughout the remainder of the study period, the NS group showed a further decline in body weight, totalling -6.2 kg by the eight week post discharge assessment (p < 0.01), whereas the S group had continued to gain weight (ns). From eight weeks to six months post discharge, both groups demonstrated a non significant increase in body weight. By the six month assessment, the S group had gained a total of +3.8 kg since the initial assessment, but the median body weight of the NS group was -4.9 kg less than the original value. The overall changes observed in body weight, from baseline to six month post discharge, were not statistically significant in either the S, or the NS group.

The difference in change in body weight between the S and NS groups was statistically significant when comparisons were made from the baseline value to; four weeks (p < 0.01), eight weeks (p < 0.001) and six months post discharge (p < 0.01).

When the changes in body weight observed in the sub-group of patients who consumed the supplements (S-C) were compared with values from their admission pairs within the NS group (NS-CP), the results were similar to those outlined above for the S and NS groups. The NS-CP group demonstrated a significant decline in bodyweight of -5.0 kgs from the initial hospital weight to the end of the period of supplementation at four weeks
post-discharge (p < 0.05). Thereafter a further decline was observed of -4.3 kgs from 4 weeks to 8 weeks post-discharge, giving a total weight loss of -9.3 kg from baseline to 8 weeks (p < 0.05). In contrast, the S-C group demonstrated a steady, non significant, increase in bodyweight of +3.3 kgs from baseline to 4 weeks post discharge with no further significant change observed between 4 and 8 weeks. This gain in body weight continued in the S-C group until, by the 6 months post discharge assessment, the group had demonstrated a net gain in weight of +5.4 kg from baseline. A similar weight gain was also noted in the NS-CP group from 8 weeks to 6 months post discharge, although the group showed an overall net loss of -8.0 kg from the initial weight. The overall changes observed in body weight, from baseline to six month post discharge, were not statistically significant in either the S-C, or the NS-CP sub group.

The difference in change in body weight between the S-C and NS-CP groups was statistically significant when comparisons were made from the baseline value to; four weeks (p < 0.01), eight weeks (p < 0.01) and 6 months (p < 0.05).
Figure 4.4a  Body weight measurements (Kg) observed in the S and NS groups from hospital to six months post-discharge.

Results are presented as median values.

Significant within-group changes from baseline: ** P<0.01

Table 4.7a  Body weight measurements (Kg) observed in the S and NS groups from hospital to six months post-discharge.

<table>
<thead>
<tr>
<th></th>
<th>Acute Hospital</th>
<th>4 weeks</th>
<th>8 weeks</th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>S</strong></td>
<td>Median</td>
<td>42.6</td>
<td>43.7</td>
<td>44.1</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>40.5</td>
<td>40.0</td>
<td>40.2</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>56.8</td>
<td>52.3</td>
<td>54.1</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>18</td>
<td>20</td>
<td>19</td>
</tr>
<tr>
<td><strong>NS</strong></td>
<td>Median</td>
<td>57.3</td>
<td>52.7</td>
<td>51.8</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>48.0</td>
<td>45.9</td>
<td>42.3</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>75.6</td>
<td>66.6</td>
<td>63.9</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>14</td>
<td>17</td>
<td>13</td>
</tr>
</tbody>
</table>

Statistical Significance

Results are presented as median values with 25th and 75th percentiles. 'n' refers to the number of patients.

Significant, between group, changes from baseline: ** P<0.01; *** P<0.001.
Figure 4.4b  Body weight measurements (Kg) observed in the S-C and NS-CP subgroups from hospital to six months post-discharge.

Results are presented as median values.

Significant within group changes from baseline: * P<0.05

Table 4.7b  Body weight measurements (Kg) observed in the S-C and NS-CP subgroups from hospital to six months post-discharge.

<table>
<thead>
<tr>
<th></th>
<th>Acute Hospital</th>
<th>4 weeks</th>
<th>8 weeks</th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>S-C</strong></td>
<td>Median</td>
<td>42.2</td>
<td>45.9</td>
<td>45.5</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>40.8</td>
<td>40.5</td>
<td>40.3</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>54.7</td>
<td>53.9</td>
<td>54.5</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>12</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td><strong>NS-CP</strong></td>
<td>Median</td>
<td>61.8</td>
<td>56.8</td>
<td>52.5</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>54.1</td>
<td>49.7</td>
<td>48.0</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>80.9</td>
<td>75.5</td>
<td>74.9</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>9</td>
<td>10</td>
<td>8</td>
</tr>
<tr>
<td>Statistical Significance</td>
<td>**</td>
<td>**</td>
<td>*</td>
<td></td>
</tr>
</tbody>
</table>

Results are presented as median values with 25th and 75th percentiles. 'n' refers to the number of patients.

Significant, between group, changes from baseline: * P<0.05; ** P<0.01.
4.4.4.2  **Triceps Skinfold Thickness (TSF)**
(Figures 4.5a and 4.5b, Tables 4.8a and 4.8b)

There were no significant changes in the TSF measurements of either the S or NS groups during the period of study, although the NS group did show a trend of increasing values following discharge from hospital (Figure 4.5a).

When the progress of the S-C group was compared with that of the NS-CP group (Figure 4.5b), again there were no significant changes either within, or between, the groups. However, a trend towards increasing values in the NS-CP group was observed from the 8 week to the six month assessment.
Figure 4.5a  Triceps skinfold thickness measurements (TSF) (mm) observed in the S and NS groups from hospital to six months post-discharge. Results are presented as median values.

Table 4.8a  Triceps skinfold thickness measurements (TSF) (mm) observed in the S and NS groups from hospital to six months post-discharge.

<table>
<thead>
<tr>
<th></th>
<th>Admission</th>
<th>Discharge</th>
<th>4 weeks</th>
<th>8 weeks</th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>S</td>
<td>Median</td>
<td>10.2</td>
<td>9.0</td>
<td>10.0</td>
<td>9.3</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>7.7</td>
<td>8.2</td>
<td>8.2</td>
<td>7.7</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>12.1</td>
<td>11.6</td>
<td>11.7</td>
<td>11.7</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>21</td>
<td>20</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>NS</td>
<td>Median</td>
<td>11.3</td>
<td>10.9</td>
<td>11.7</td>
<td>12.7</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>8.9</td>
<td>7.1</td>
<td>7.3</td>
<td>8.6</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>15.7</td>
<td>17.0</td>
<td>15.6</td>
<td>16.3</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>21</td>
<td>21</td>
<td>19</td>
<td>14</td>
</tr>
<tr>
<td>Statistical Significance</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
</tr>
</tbody>
</table>

Results are presented as median values with 25th and 75th percentiles. 'n' refers to the number of patients.
Figure 4.5b  Triceps skinfold thickness measurements (TSF) (mm) observed in the S-C and NS-CP sub groups from hospital to six months post-discharge.

Results are presented as median values.

Table 4.8b  Triceps skinfold thickness measurements (TSF) (mm) observed in the S-C and NS-CP sub groups from hospital to six months post-discharge.

<table>
<thead>
<tr>
<th></th>
<th>Admission</th>
<th>Discharge</th>
<th>4 weeks</th>
<th>8 weeks</th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>S-C</td>
<td>Median</td>
<td>10.6</td>
<td>9.2</td>
<td>10.5</td>
<td>10.7</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>8.2</td>
<td>8.3</td>
<td>7.2</td>
<td>7.1</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>13.2</td>
<td>11.9</td>
<td>12.2</td>
<td>11.8</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>13</td>
<td>13</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td>NS-CP</td>
<td>Median</td>
<td>12.9</td>
<td>14.2</td>
<td>13.5</td>
<td>12.9</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>8.2</td>
<td>7.8</td>
<td>8.7</td>
<td>9.9</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>17.1</td>
<td>17.8</td>
<td>16.8</td>
<td>16.9</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>13</td>
<td>13</td>
<td>11</td>
<td>9</td>
</tr>
<tr>
<td>Statistical Significance</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
</tr>
</tbody>
</table>

Results are presented as median values with 25th and 75th percentiles. 'n' refers to the number of patients.
4.4.4.3 Mid Upper Arm Circumference (MUAC)
(Figures 4.6a and 4.6b, Tables 4.9a and 4.9b)

A gradual decline in the MUAC measurement was observed in the NS group, the 8 week and 6 month values being significantly lower than the admission value (both $p < 0.01$). The greatest decline, a difference in median values of -1.8 cm, was observed between the four and eight week post discharge assessments.

The S group demonstrated a significant decline in MUAC of -1.6 cm ($p < 0.05$) from admission to discharge, after which an increase in MUAC was observed, such that none of the post-discharge measurements were significantly different from the admission value.

When the changes in MUAC were compared from the admission value, the differences between the S and NS groups, were significant at discharge ($p < 0.05$), 4 weeks ($p < 0.01$), 8 weeks ($p < 0.01$) and 6 months ($p < 0.01$).

The S-C group did not demonstrate any statistically significant changes from admission to any of the time periods assessed. In contrast to this, the NS-CP group demonstrated a significant decline in MUAC from admission to 8 weeks post-discharge ($p < 0.01$). This was then followed by an increase in MUAC resulting in the 6 months post-discharge measurement being significantly greater than the admission measurement ($p < 0.05$).

Changes in MUAC from the admission value of the S-C group, compared with the NS-CP group, were significantly different at the 8 weeks ($p < 0.01$) and 6 month ($p < 0.05$) assessment.
Figure 4.6a  Mid upper arm circumference measurements (MUAC (cm)) observed in the S and NS groups from hospital to six months post-discharge.

Results are presented as median values.

Significant within-group changes from baseline: * P<0.05; ** P<0.01.

Table 4.9a  Mid upper arm circumference measurements (MUAC) (cm) observed in the S and NS groups from hospital to six months post-discharge.

<table>
<thead>
<tr>
<th></th>
<th>Admission</th>
<th>Discharge</th>
<th>4 weeks</th>
<th>8 weeks</th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>S</strong></td>
<td>Median</td>
<td>24.0</td>
<td>22.4</td>
<td>23.4</td>
<td>24.0</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>21.9</td>
<td>21.7</td>
<td>21.4</td>
<td>21.3</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>27.4</td>
<td>26.9</td>
<td>26.7</td>
<td>27.5</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>21</td>
<td>20</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td><strong>NS</strong></td>
<td>Median</td>
<td>28.9</td>
<td>28.8</td>
<td>28.7</td>
<td>26.9</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>24.4</td>
<td>22.4</td>
<td>23.4</td>
<td>24.0</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>33.7</td>
<td>32.3</td>
<td>30.0</td>
<td>30.3</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>21</td>
<td>21</td>
<td>19</td>
<td>14</td>
</tr>
</tbody>
</table>

Statistical Significance

Results are presented as median values with 25th and 75th percentiles. 'n' refers to the number of patients.

Significant, between group, changes from baseline: * P<0.05; ** P<0.01.
Figure 4.6b. Mid upper arm circumference measurements (MUAC) (cm) observed in the S-C and NS-CP sub groups from hospital to six months post-discharge.

Results are presented as median values.

Significant within-group changes from baseline: * P<0.05; ** P<0.01

Table 4.9b Mid upper arm circumference measurements (MUAC) (cm) observed in the S-C and NS-CP sub groups from hospital to six months post-discharge.

<table>
<thead>
<tr>
<th></th>
<th>Admission</th>
<th>Discharge</th>
<th>4 weeks</th>
<th>8 weeks</th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>S-C</strong></td>
<td>Median</td>
<td>26.0</td>
<td>24.9</td>
<td>24.6</td>
<td>24.5</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>21.5</td>
<td>21.8</td>
<td>21.4</td>
<td>21.3</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>27.4</td>
<td>27.1</td>
<td>27.0</td>
<td>27.9</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>13</td>
<td>13</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td><strong>NS-CP</strong></td>
<td>Median</td>
<td>28.9</td>
<td>29.5</td>
<td>29.1</td>
<td>28.1</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>25.6</td>
<td>23.3</td>
<td>24.0</td>
<td>24.5</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>33.7</td>
<td>33.6</td>
<td>31.0</td>
<td>31.8</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>13</td>
<td>13</td>
<td>11</td>
<td>9</td>
</tr>
</tbody>
</table>

Statistical Significance ns ns ** ns

Results are presented as median values with 25th and 75th percentiles. 'n' refers to the number of patients.

Significant, between group, changes from baseline: ** P<0.01.
4.4.4.4 Mid Upper Arm Muscle Circumference (MAUMC).

(Figures 4.7a and 4.7b, Tables 4.10a and 4.10b)

Both the NS and S groups demonstrated a significant decline in MUAMC measurements from admission to discharge (p < 0.01 and p < 0.05 respectively). In the S group, this decline reached a plateau from discharge to 8 weeks with values returning to a value which was not significantly different from the admission median measurement, by 6 months post-discharge. In contrast, the median MUAMC measurement of the NS group continued to decline, the eight week value being significantly lower than the admission value (p < 0.01). There was no significant change from the 8 week to the 6 month value (p > 0.01), but the 6 month value was significantly lower than the admission measurement (p < 0.01).

The differences in change between the S and NS groups were significant from admission to discharge (p < 0.05), from admission to 8 weeks and from admission to 6 months post-discharge (all p < 0.01).

In the S-C group there were no significant changes from admission to any of the post-discharge measurements. In contrast, the NS-CP group showed a consistent decline in all MUAMC measurements from the admission value, reaching statistical significance by 4 weeks (p < 0.05), 8 weeks (p < 0.01) and 6 months (p < 0.01) post discharge. The difference in median values from admission to discharge being -2.3 cm.

When the changes from admission to each of the time periods were compared between the S-C and NS-CP groups, these were significantly different at 8 weeks and 6 months post discharge (both p < 0.01).
Figure 4.7a  **Mid upper arm muscle circumference measurements (MUAMC) (cm)** observed in the S and NS groups from hospital to six months post-discharge.

Results are presented as median values.

Significant within group changes from baseline: * P<0.05; ** P<0.01.

<table>
<thead>
<tr>
<th></th>
<th>Admission</th>
<th>Discharge</th>
<th>4 weeks</th>
<th>8 weeks</th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>S</td>
<td>Median</td>
<td>21.1</td>
<td>20.2</td>
<td>20.3</td>
<td>20.4</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>19.2</td>
<td>18.7</td>
<td>18.8</td>
<td>18.9</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>24.6</td>
<td>23.9</td>
<td>23.5</td>
<td>24.3</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>21</td>
<td>20</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>NS</td>
<td>Median</td>
<td>24.5</td>
<td>24.1</td>
<td>23.0</td>
<td>22.7</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>20.5</td>
<td>19.5</td>
<td>19.7</td>
<td>20.2</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>27.7</td>
<td>27.1</td>
<td>26.0</td>
<td>25.5</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>21</td>
<td>21</td>
<td>19</td>
<td>14</td>
</tr>
</tbody>
</table>

Statistical Significance

Results are presented as median values with 25th and 75th percentiles. 'n' refers to the number of patients.

Significant, between group, changes from baseline: * P<0.05.
Figure 4.7b Mid upper arm muscle circumference measurements (MUAMC) (cm) observed in the S-C and NS-CP sub groups from hospital to six months post-discharge.

Results are presented as median values.

Significant within-group changes from baseline: * P<0.05.

Table 4.10b Mid upper arm muscle circumference measurements (MUAMC) (cm) observed in the S-C and NS-CP sub groups from hospital to six months post-discharge.

<table>
<thead>
<tr>
<th></th>
<th>Admission</th>
<th>Discharge</th>
<th>4 weeks</th>
<th>8 weeks</th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>S-C</strong></td>
<td>Median</td>
<td>21.1</td>
<td>20.7</td>
<td>20.4</td>
<td>21.9</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>18.9</td>
<td>19.3</td>
<td>19.2</td>
<td>19.2</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>24.3</td>
<td>23.6</td>
<td>24.5</td>
<td>24.5</td>
</tr>
<tr>
<td></td>
<td><em>n</em></td>
<td>13</td>
<td>13</td>
<td>13</td>
<td>12</td>
</tr>
<tr>
<td><strong>NS-CP</strong></td>
<td>Median</td>
<td>26.1</td>
<td>24.3</td>
<td>24.0</td>
<td>23.8</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>21.6</td>
<td>19.9</td>
<td>20.8</td>
<td>21.5</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>27.7</td>
<td>26.7</td>
<td>26.6</td>
<td>26.2</td>
</tr>
<tr>
<td></td>
<td><em>n</em></td>
<td>13</td>
<td>13</td>
<td>11</td>
<td>8</td>
</tr>
</tbody>
</table>

Statistical Significance ns

Results are presented as median values with 25th and 75th percentiles. 'n' refers to the number of patients.

Significant, between group, changes from baseline: * P<0.05.
4.4.5 Changes in serum albumin and retinol binding protein from admission to 6 months post-discharge.

The changes in serum albumin and retinol binding protein from admission to six months post-discharge are presented in Figures 4.8a to 4.9a for the two study groups (S and NS) and Figures 4.8b to 4.9b for the sub-groups (S-C and NS-CP). The numerical data are also presented beneath the figures in Tables 4.11.a to 4.12.a (S and NS) and 4.11.b to 4.11.b (S-C and NS-CP).

4.4.5.1 Serum albumin (ALB)

(Figures 4.8a and 4.8b, Tables 4.11a and 4.11b).

From admission to discharge, there was a non-significant decline in median albumin values in both the NS and S groups. Following discharge from hospital, there was a significant increase in albumin concentration in the S group from admission to 4 weeks post-discharge (p < 0.01) which was maintained at the 6 months post-discharge assessment (p < 0.01 from the admission value). There was also an increase in the median serum albumin concentration of the NS group from discharge to 4 weeks, by which time the serum albumin was not significantly different from the admission value. There was no further significant change in serum albumin concentration of the NS group from four weeks to six months post discharge.

The difference in change between the S and NS groups was significant from admission to 4 weeks (p < 0.05).

When the S-C group median values were compared to the NS-CP median group values, in both groups there was a non-significant fall in serum albumin value from admission to discharge. After discharge, there was a significant increase from discharge to 4 weeks post-discharge in the S-C group (p < 0.05, from admission) which was maintained at 6 months post-discharge (P < 0.05, from admission). In contrast, there were no significant
changes in the NS-CP group, from admission to any of the time periods assessed.

The differences in change over time between the two groups were not significant for any of the time periods assessed.
Figure 4.8a: Serum albumin (g/dl) measurements observed in the S and NS groups from hospital to six months post-discharge.

Results are presented as median values.

Significant within group changes from baseline: * P<0.05; ** P<0.01.

Table 4.11a: Serum albumin (g/dl) measurements observed in the S and NS groups from hospital to six months post-discharge.

<table>
<thead>
<tr>
<th></th>
<th>Admission</th>
<th>Discharge</th>
<th>4 weeks</th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>S</strong></td>
<td>Median</td>
<td>39.0</td>
<td>36.5</td>
<td>43.5</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>35.8</td>
<td>34.8</td>
<td>39.3</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>45.3</td>
<td>41.0</td>
<td>47.8</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>18</td>
<td>14</td>
<td>16</td>
</tr>
<tr>
<td><strong>NS</strong></td>
<td>Median</td>
<td>43.0</td>
<td>40.0</td>
<td>42.0</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>39.0</td>
<td>34.0</td>
<td>36.5</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>46.0</td>
<td>45.5</td>
<td>45.5</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>16</td>
<td>13</td>
<td>17</td>
</tr>
</tbody>
</table>

Statistical Significance: ns ns ns ns

Results are presented as median values with 25th and 75th percentiles. 'n' refers to the number of patients.
Figure 4.8b. Serum albumin (g/dl) measurements observed in the S-C and NS-CP sub groups from hospital to six months post-discharge.

Results are presented as median values.

Significant within group changes from baseline: (*) P=0.05; * P<0.05.

<table>
<thead>
<tr>
<th></th>
<th>Admission</th>
<th>Discharge</th>
<th>4 weeks</th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>S-C</strong></td>
<td>Median</td>
<td>40.5</td>
<td>36.0</td>
<td>43.5</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>30.5</td>
<td>34.5</td>
<td>39.3</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>46.0</td>
<td>40.5</td>
<td>48.5</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>10</td>
<td>9</td>
<td>12</td>
</tr>
<tr>
<td><strong>NS-CP</strong></td>
<td>Median</td>
<td>44.0</td>
<td>42.5</td>
<td>42.0</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>40.0</td>
<td>33.0</td>
<td>37.5</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>51.5</td>
<td>47.0</td>
<td>47.0</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>9</td>
<td>6</td>
<td>9</td>
</tr>
<tr>
<td>Statistical Significance</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
</tr>
</tbody>
</table>

Results are presented as median values with 25th and 75th percentiles. 'n' refers to the number of patients.
4.4.5.2 Retinol Binding Protein (RBP)
(Figures 4.9a and 4.9b, Tables 4.12a and 4.12b)
The S group demonstrated a significant increase in median serum RBP, of 10.0 mg/l, from admission to 4 weeks post-discharge (p < 0.05), which was maintained at 6 months after discharge. In contrast, there were no changes in the serum RBP value of the NS group, until between the 4 week and 6 month post discharge assessment when an increase of 8.5 mg/l was observed. This change was not statistically significant.

When the changes were compared between the S and NS groups, there were no significant differences.

The S-C group demonstrated a significant increase in RBP, of 18.5 mg/l, from admission to 4 weeks post-discharge (p < 0.05), the serum RBP at 6 months being significantly greater than the admission value (p < 0.05).

When the changes were compared between the S-C and NS-CP groups, there was a significant difference in change from admission to 4 weeks post discharge (p < 0.05).
Figure 4.9a  Serum retinol binding protein measurements (RBP) (mg/l) observed in the S and NS groups from hospital to six months post-discharge.

Results are presented as median values.

Significant within group changes from baseline: * P<0.05.

Table 4.12a  Serum retinol binding protein measurements (RBP) (mg/l) observed in the S and NS groups from hospital to six months post-discharge.

<table>
<thead>
<tr>
<th></th>
<th>Admission</th>
<th>Discharge</th>
<th>4 weeks</th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>S</td>
<td>Median</td>
<td>37.0</td>
<td>43.0</td>
<td>47.0</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>32.5</td>
<td>30.5</td>
<td>39.0</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>46.3</td>
<td>60.0</td>
<td>64.0</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>18</td>
<td>14</td>
<td>17</td>
</tr>
<tr>
<td>NS</td>
<td>Median</td>
<td>47.5</td>
<td>47.0</td>
<td>47.0</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>40.3</td>
<td>37.5</td>
<td>42.0</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>58.0</td>
<td>62.5</td>
<td>56.0</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>16</td>
<td>13</td>
<td>17</td>
</tr>
</tbody>
</table>

Statistical Significance: ns

Results are presented as median values with 25th and 75th percentiles. 'n' refers to the number of patients.
Figure 4.9b. Serum retinol binding protein measurements (RBP) (mg/l) observed in the S-C and NS-CP sub groups from hospital to six months post-discharge.

Results are presented as median values.

Significant within-group changes from baseline: * P<0.05.

Table 4.12b. Serum retinol binding protein measurements (RBP) (mg/l) observed in the S-C and NS-CP sub groups from hospital to six months post-discharge.

<table>
<thead>
<tr>
<th></th>
<th>Admission</th>
<th>Discharge</th>
<th>4 weeks</th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>S-C</td>
<td>Median</td>
<td>37.0</td>
<td>45.0</td>
<td>54.5</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>29.5</td>
<td>30.0</td>
<td>38.0</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>41.5</td>
<td>59.0</td>
<td>71.8</td>
</tr>
<tr>
<td>n</td>
<td>10</td>
<td>9</td>
<td>12</td>
<td>11</td>
</tr>
<tr>
<td>NS-CP</td>
<td>Median</td>
<td>51.0</td>
<td>53.5</td>
<td>47.0</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>43.5</td>
<td>37.8</td>
<td>42.0</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>61.5</td>
<td>67.0</td>
<td>59.0</td>
</tr>
<tr>
<td>n</td>
<td>9</td>
<td>6</td>
<td>9</td>
<td>6</td>
</tr>
<tr>
<td>Statistical Significance</td>
<td>ns</td>
<td>*</td>
<td>ns</td>
<td></td>
</tr>
</tbody>
</table>

Results are presented as median values with 25th and 75th percentiles. 'n' refers to the number of patients.

Significant, between group, changes from baseline: * P<0.05.
4.4.6 Changes in voluntary Hand Grip Strength (vHGS) from admission to 6 months post-discharge

The changes in voluntary hand grip strength (vHGS) from admission to six months post-discharge are presented in Figure 4.10a. for the two study groups (S and NS) and Figure 4.10b. for the sub-groups (S-C and NS-CP). The numerical data are also presented beneath the figures in Table 4.13a (S and NS) and 4.13b to (S-C and NS-CP).

Over the period of study, there were no significant changes in vHGS of the S group, from the admission value. The NS group demonstrated a trend of declining vHGS from the admission value until 4 weeks post-discharge, followed by a trend of increase in vHGS from 4 weeks to 6 months post-discharge, but none of these changes were statistically significantly different from the admission value.

A similar trend was observed in the NS-CP group to that of the NS group, none of the changes being statistically significant.

In the S-C group, a steady increase in vHGS was noted from admission, until statistical significance was reached at 8 weeks post-discharge (p < 0.05). This was followed by a decline in vHGS, until the value at the 6 months assessment was not statistically higher than the admission value.

There were no statistically significant differences between the changes of the S and NS groups, nor between the S-C and NS-CP groups.
Figure 4.10a Voluntary hand grip strength measurements (vHGS) (lb/in²) observed in the S and NS groups from hospital to six months post-discharge. Results are presented as median values.

Table 4.13a Voluntary hand grip strength measurements (vHGS) (lb/in²) observed in the S and NS groups from hospital to six months post-discharge.

<table>
<thead>
<tr>
<th></th>
<th>Admission</th>
<th>Discharge</th>
<th>4 weeks</th>
<th>8 weeks</th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>S</td>
<td>Median</td>
<td>1.00</td>
<td>2.00</td>
<td>1.75</td>
<td>2.00</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>0.25</td>
<td>0.50</td>
<td>0.875</td>
<td>0.125</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>4.00</td>
<td>4.125</td>
<td>5.00</td>
<td>4.875</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>21</td>
<td>20</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>NS</td>
<td>Median</td>
<td>3.00</td>
<td>2.50</td>
<td>1.75</td>
<td>4.00</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>1.25</td>
<td>1.25</td>
<td>0.50</td>
<td>0.01</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>5.00</td>
<td>5.00</td>
<td>4.25</td>
<td>6.00</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>21</td>
<td>21</td>
<td>18</td>
<td>15</td>
</tr>
<tr>
<td>Statistical Significance</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
</tr>
</tbody>
</table>

Results are presented as median values with 25th and 75th percentiles. 'n' refers to the number of patients.
Figure 4.1b  Voluntary hand grip strength measurements (vHGS) (lb/in²) observed in the S-C and NS-CP sub groups from hospital to six months post-discharge.

Results are presented as median values.

Significant within-group changes from baseline: * P<0.05.

Table 4.13b  Voluntary hand grip strength measurements (vHGS) (lb/in²) observed in the S-C and NS-CP sub groups from hospital to six months post-discharge.

<table>
<thead>
<tr>
<th></th>
<th>Admission</th>
<th>Discharge</th>
<th>4 weeks</th>
<th>8 weeks</th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>S-C</td>
<td>Median</td>
<td>1.00</td>
<td>1.50</td>
<td>2.00</td>
<td>3.00</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>0.00</td>
<td>0.50</td>
<td>0.50</td>
<td>0.25</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>4.00</td>
<td>4.00</td>
<td>5.25</td>
<td>5.50</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>13</td>
<td>13</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td>NS-CP</td>
<td>Median</td>
<td>4.00</td>
<td>3.00</td>
<td>1.50</td>
<td>4.00</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>1.25</td>
<td>1.25</td>
<td>0.50</td>
<td>0.00</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>5.00</td>
<td>5.00</td>
<td>5.00</td>
<td>6.25</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>13</td>
<td>13</td>
<td>11</td>
<td>10</td>
</tr>
</tbody>
</table>

Statistical Significance ns ns ns ns ns

*Results are presented as median values with 25th and 75th percentiles. 'n' refers to the number of patients.
4.4.7 Changes in mental function (CAPE score) from admission to 6 months post-discharge

The changes in mental function (CAPE score) from admission to six months post-discharge are presented in Figure 4.11a for the two study groups (S and NS) and Figures 4.11b for the sub-groups (S-C and NS-CP). The numerical data are also presented beneath the figures in Tables 4.14a (S and NS) and 4.14b (S-C and NS-CP).

There were no significant changes from the admission values to any of the time periods assessed in either the S or NS group, nor the S-C or NS-CP sub groups. However, in the S, NS and NS-CP groups, the median admission score was lower than post-discharge scores (non-significant). In all groups, the median value at 6 months post-discharge was 100%.
Figure 4.11a  Mental function test score (MFT) (%) in the S and NS groups from hospital to six months post-discharge.

Results are presented as median values.

Table 4.14a  Mental function test score (MFT) (%) in the S and NS groups from hospital to six months post-discharge.

<table>
<thead>
<tr>
<th></th>
<th>Acute Hospital</th>
<th>4 weeks</th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>S</td>
<td>Median</td>
<td>95.7</td>
<td>100.0</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>78.3</td>
<td>89.1</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>100.0</td>
<td>100.0</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>21</td>
<td>20</td>
</tr>
<tr>
<td>NS</td>
<td>Median</td>
<td>91.3</td>
<td>100.0</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>82.6</td>
<td>91.3</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>100.0</td>
<td>100.0</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>21</td>
<td>16</td>
</tr>
<tr>
<td>Statistical Significance</td>
<td></td>
<td>ns</td>
<td>ns</td>
</tr>
</tbody>
</table>
Table 4.14b. Mental function test score (MFT) (%) observed in the S-C and NS-CP subgroups from hospital to six months post-discharge.

<table>
<thead>
<tr>
<th></th>
<th>Acute Hospital</th>
<th>4 weeks</th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>S-C</td>
<td>Median 100.0</td>
<td>100.0</td>
<td>100.0</td>
</tr>
<tr>
<td></td>
<td>25th percentile 91.3</td>
<td>95.7</td>
<td>95.7</td>
</tr>
<tr>
<td></td>
<td>75th percentile 100.0</td>
<td>100.0</td>
<td>100.0</td>
</tr>
<tr>
<td></td>
<td>n 13</td>
<td>13</td>
<td>12</td>
</tr>
<tr>
<td>NS-CP</td>
<td>Median 91.3</td>
<td>97.8</td>
<td>100.0</td>
</tr>
<tr>
<td></td>
<td>25th percentile 84.8</td>
<td>88.0</td>
<td>90.2</td>
</tr>
<tr>
<td></td>
<td>75th percentile 100.0</td>
<td>100.0</td>
<td>100.0</td>
</tr>
<tr>
<td></td>
<td>n 13</td>
<td>10</td>
<td>6</td>
</tr>
</tbody>
</table>

Statistical Significance ns ns ns

Results are presented as median values with 25th and 75th percentiles. 'n' refers to the number of patients.
4.4.8 Clinical outcome data

4.4.8.1 Duration of stay and place to which discharged from the acute hospital

The data for the durations of stay are presented in Figure 4.12a (S and NS) and 4.12b (S-C and NS-CP), with the corresponding numerical data presented in Tables 4.15a (S and NS) and 4.15b (S-C and NS-CP).

There was no significant difference between the total duration of stay in the acute hospital (from admission to discharge) between the S (median stay = 16 days) and NS groups (median stay = 18 days). When pre-operative waiting time was not included in the duration (i.e., duration from the day of operation until discharge), there was still no significant difference between the S (median stay = 15 days) and NS groups (median stay = 16 days).

Following discharge from the acute hospital, a greater number of patients in the NS group required a further period of convalescence in another hospital (n = 13), compared with the S group (n = 10), although this difference was not statistically significant. The median duration of stay in the convalescence hospital was significantly greater in the NS group (16 days) than in the S group (7 days), \( p < 0.05 \) and the sum total of days spent in the acute and convalescence hospitals was greater in the NS group (33 days) than in the S group (22 days) \( p < 0.08 \).

When the data from the S-C sub-group were compared with that of the NS-CP sub-group, the median duration of stay in the acute hospital (admission to discharge) was significantly less in the S-C group (14 days) compared with the NS-CP group (18 days) \( p < 0.05 \). When the pre-operative waiting times were excluded (i.e., time from operation to discharge) the median stay was still less in the S-C group (13 days) than in the NS-CP group (16 days),
although this difference was not statistically significant. In the S-C sub-
group 5 patients required a period of convalescence in another hospital,
compared with 10 patients in the NS-CP sub-group. The median time spent
in a convalescent hospital was significantly greater in the NS-CP group (24
days) compared with the S-C group (6 days), (p < 0.01) and the sum total
median stay in the acute and convalescent hospitals was significantly
greater in the NS-CP (43 days), compared with 16 days in the S-C group (p
< 0.001).
Figure 4.12a  Duration of stay in hospital (acute, convalescence and total) experienced by the S and NS groups.

Results are presented as median values with 25th and 75th percentiles represented by the bar.

Table 4.15a  Duration of stay in hospital (acute, convalescence and total) experienced by the S and NS groups.

<table>
<thead>
<tr>
<th></th>
<th>Acute Hospital</th>
<th>Convalescence Hospital</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>S</td>
<td>Median</td>
<td>16.0</td>
<td>7.0</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>11.0</td>
<td>0.0</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>25.0</td>
<td>25.5</td>
</tr>
<tr>
<td>n</td>
<td>21</td>
<td>10</td>
<td>21</td>
</tr>
<tr>
<td>NS</td>
<td>Median</td>
<td>18.0</td>
<td>16.0</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>11.0</td>
<td>0.0</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>25.0</td>
<td>36.5</td>
</tr>
<tr>
<td>n</td>
<td>21</td>
<td>13</td>
<td>21</td>
</tr>
</tbody>
</table>

Statistical Significance

Results are presented as median values with 25th and 75th percentiles. 'n' refers to the number of patients.

Values Significantly different between groups; * P<0.05; + P<0.08, close to statistical significance.
Figure 4.12b  Duration of stay in hospital (acute, convalescence and total) experienced by the S-C and NS-CP sub groups.

Results are presented as median values with the 25th and 75th percentiles represented by the bar.

Table 4.15b  Duration of stay in hospital (acute, convalescence and total) experienced by the S-C and NS-CP sub groups.

<table>
<thead>
<tr>
<th></th>
<th>Acute Hospital</th>
<th>Convalescence Hospital</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>S-C</td>
<td>Median 14.0</td>
<td>6.0</td>
<td>16.0</td>
</tr>
<tr>
<td></td>
<td>25th percentile 8.5</td>
<td>0.0</td>
<td>14.5</td>
</tr>
<tr>
<td></td>
<td>75th percentile 18.0</td>
<td>18.5</td>
<td>27.0</td>
</tr>
<tr>
<td></td>
<td>n 13</td>
<td></td>
<td>13</td>
</tr>
<tr>
<td>NS-CP</td>
<td>Median 18.0</td>
<td>24.0</td>
<td>43.0</td>
</tr>
<tr>
<td></td>
<td>25th percentile 15.5</td>
<td>3.5</td>
<td>24.5</td>
</tr>
<tr>
<td></td>
<td>75th percentile 24.5</td>
<td>50.0</td>
<td>61.5</td>
</tr>
<tr>
<td></td>
<td>n 13</td>
<td></td>
<td>13</td>
</tr>
</tbody>
</table>

Results are presented as median values with 25th and 75th percentiles. 'n' refers to the number of patients.

Values significantly different between groups: * P<0.05; ** P<0.01; *** P<0.001.
4.4.8.2 Place of living and independence of mobility (modified VISICK score) at subsequent assessment periods following discharge from the acute hospital.

Data for the place of living at the time periods of assessment following discharge from the acute hospital are presented in Table 4.16a and 4.16b. Data on the index of independence of performing the activities of daily living (modified VISICK score) for each of the time periods is presented in Figures 4.13a (S and NS) and 4.13b (S-C and NS-CP), with the numerical data beneath in Tables 4.17a (S and NS) and 4.17b (S-C and NS-CP).

The number of patients who were living a relatively independent lifestyle prior to admission to hospital were similar in the S (n=10) and NS (n=13) groups, as were the number of patients who had returned to this way of living by the end of the period of study (9 of the S group and 11 of the NS group). The one patient in the S group who had not returned to her previously independent way of living was in a residential home at 6 months post-discharge and the two patients in the NS group had both died.

Of the 8 patients in the S group who were admitted from either warden controlled accommodation or the care of relatives, 5 had returned to these circumstances by the end of the period of study. One patient had returned to her original warden controlled flat by 4 weeks post discharge, but was then readmitted to the RSCH at 6 months, with a dislocated shoulder; one patient who was admitted from the care of relatives had moved to a residential home; and one patient had died whilst in the acute hospital.

Of the 4 patients in the NS group who were admitted from either warden controlled accommodation or the care of relatives, 2 had returned to these circumstances by the end of the period of study. One patient had moved to a residential home and one patient had died shortly after discharge from the acute hospital.
Table 4.16a

Place of living at the time periods of assessment following discharge from the acute hospital, for the S and NS groups

<table>
<thead>
<tr>
<th>Place</th>
<th>Admission</th>
<th>Discharge</th>
<th>4 weeks post-discharge</th>
<th>8 weeks post-discharge</th>
<th>6 months post-discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>S</td>
<td>NS</td>
<td>S</td>
<td>NS</td>
<td>S</td>
</tr>
<tr>
<td>LI</td>
<td>10</td>
<td>13</td>
<td>6</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>WC</td>
<td>4</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>RC</td>
<td>4</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>RH</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>CH</td>
<td>0</td>
<td>0</td>
<td>7</td>
<td>7</td>
<td>4</td>
</tr>
<tr>
<td>TH</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>RSCH</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>21</td>
<td>21</td>
<td>20</td>
<td>21</td>
<td>20</td>
</tr>
</tbody>
</table>

Key:
- LI  Living independently
- WC  Warden controlled
- RC  Relatives care
- RH  Residential Home
- CH  Convalescence Hospital
- TH  Transfer Hospital
- RSCH Readmitted to RSCH

D  Deceased
M  Moved

(1 D)  (2 D)  (3 D)  (1 M)  (2 D)  (3 D)  (1 M)
Table 4.16b

Place of living at the time periods of assessment following discharge from the acute hospital for the S-C and NS-CP sub-groups

<table>
<thead>
<tr>
<th>Place</th>
<th>Admission</th>
<th>Discharge</th>
<th>4 weeks post-discharge</th>
<th>8 weeks post-discharge</th>
<th>6 months post-discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>S-C</td>
<td>NS-CP</td>
<td>S-C</td>
<td>NS-CP</td>
<td>S-C</td>
</tr>
<tr>
<td>LI</td>
<td>7</td>
<td>9</td>
<td>5</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>WC</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>RC</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>RH</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>CH</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>TH</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>RSCH</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>13</td>
<td>13</td>
<td>13</td>
<td>13</td>
<td>13</td>
</tr>
</tbody>
</table>

Key:
- LI Living independently
- WC Warden controlled
- RC Relatives care
- RH Residential Home
- CH Convalescence Hospital
- TH Transfer Hospital
- RSCH Readmitted to RSCH
- D Deceased
Figure 4.13a  VISICK SCORE in the S and NS groups from 1 week to six months post-discharge.

Results are presented as median values.

<table>
<thead>
<tr>
<th></th>
<th>1 week</th>
<th>4 weeks</th>
<th>8 weeks</th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>S</strong></td>
<td>Median</td>
<td>3.0</td>
<td>2.0</td>
<td>2.0</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>2.0</td>
<td>1.5</td>
<td>1.0</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>3.0</td>
<td>3.0</td>
<td>2.0</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>21</td>
<td>21</td>
<td>21</td>
</tr>
<tr>
<td><strong>NS</strong></td>
<td>Median</td>
<td>3.0</td>
<td>3.0</td>
<td>3.0</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>3.0</td>
<td>2.0</td>
<td>1.0</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>4.0</td>
<td>4.0</td>
<td>4.0</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>21</td>
<td>21</td>
<td>21</td>
</tr>
</tbody>
</table>

Statistical Significance: ns ns ns

Results are presented as median values with 25th and 75th percentiles. 'n' refers to the number of patients.
Figure 4.13b VISICK SCORE in the S-C and NS-CP sub groups from 1 week to six months post-discharge.

Results are presented as median values.

Significant within-group changes from baseline: * P<0.05.

Table 4.17b VISICK SCORE in the S-C and NS-CP groups from 1 week to six months post-discharge.

<table>
<thead>
<tr>
<th></th>
<th>1 week</th>
<th>4 weeks</th>
<th>8 weeks</th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>S-C</td>
<td>median</td>
<td>3.0</td>
<td>2.0</td>
<td>2.0</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>2.0</td>
<td>1.0</td>
<td>0.5</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>3.0</td>
<td>3.0</td>
<td>2.0</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>13</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td>NS-CP</td>
<td>median</td>
<td>3.0</td>
<td>3.0</td>
<td>3.0</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>3.0</td>
<td>2.0</td>
<td>1.0</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>4.0</td>
<td>4.0</td>
<td>4.75</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>13</td>
<td>13</td>
<td>12</td>
</tr>
<tr>
<td>Statistical Significance</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
</tr>
</tbody>
</table>

Results are presented as median values with 25th and 75th percentiles. 'n' refers to the number of patients.
Of the 3 patients in the S group and 4 patients in the NS group who were already living in a residential home prior to admission, two in each of the groups had returned to these circumstances during the period of study. One patient from the NS group had moved away from the area and her situation was unknown, whilst the other two patients had died.

As previously mentioned, 10 patients from the S group were discharged to another hospital compared with 13 patients from the NS group (see section above), but by 4 weeks post-discharge 14 patients in the S group had returned to their original circumstances compared with 9 of the NS group.

When the circumstances of living of the S-C sub-group are compared with those of the NS-CP sub-group, 12 (92%) of the S-C patients had returned to their original circumstances by 8 weeks post-discharge compared with only 6 (46%) of the NS-CP group by the same assessment time. One patient in the S-C sub-group had been moved to a residential home, whereas 3 of the patients in the NS-CP group had died, 3 were convalescing at another hospital and one had been readmitted to the RSCH with a broken ankle and subsequently died of an embolism.

The level of independence at the times of assessment is reflected by the VISICK score. The higher the VISICK score, the higher the degree of dependence, thus the lower the score, the more independent the patient is.

As shown in Figure 4.13a, there were no significant changes in VISICK score from discharge to six months post discharge, in either the S or NS groups. However, both showed trends towards an improvement in independence following discharge. There were no significant differences between the S and NS groups in the changes in VISICK score at any of the time points.
In the S-C group (Figure 4.13b), there was a significant improvement in VISICK score between the immediate discharge and the six month post discharge assessment ($p < 0.05$), with a similar but less marked trend in the NS-CP group. There were no significant differences between the groups in the changes in VISICK score at any time point.

4.4.8.3 **Complications**

The complication rates experienced by patients during the period of study are presented in Table 4.18.

One of the patients in the S group and two patients in the NS group experienced complications during the period of stay in the acute hospital, which were technical in nature and related to the initial surgical procedure. Following discharge from the acute hospital, two patients in the S group required readmission to the RSCH (one related to the initial prosthesis and one for a dislocated shoulder) as did two patients from the NS group (one for a total knee replacement and one for treatment to a broken ankle).

One patient in the S group and two patients in the NS group suffered one or more falls after discharge from the acute hospital. (It was one of these falls which resulted in the broken ankle in one of the patients in the NS group.) Four patients in each of the S and NS groups contracted urinary tract infections (UTI's) in the post-operative period; one patient in the S group contracted a chest infection compared with 6 in the NS group, two of which developed into pneumonia; one patient in the S group had a wound infection diagnosed, compared with 4 patients in the NS group. The incidence of pressure sores in the NS group (14 patients) was twice as great as that in the S group (7 patients) ($p < 0.01$).
### Table 4.18

**Number of patients experiencing complications during the period of study, in the S and NS groups and the S-C and NS-CP sub-groups.**

<table>
<thead>
<tr>
<th>Complication</th>
<th>S</th>
<th>NS</th>
<th>S-C</th>
<th>NS-CP</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fall(s) after discharge from the acute hospital</strong></td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td><strong>Infection:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UTI</td>
<td>4</td>
<td>4</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Chest infection</td>
<td>1 (0)</td>
<td>6 (2) *</td>
<td>1 (0)</td>
<td>4 (1) *</td>
</tr>
<tr>
<td>(# Pneumonia)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wound (surface/internal)</td>
<td>1</td>
<td>1</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td><strong>Pressure sores</strong></td>
<td>7</td>
<td>14 **</td>
<td>3</td>
<td>9 **</td>
</tr>
<tr>
<td><strong>Surgical complications</strong></td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>0</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>(1 SR, 1 DT)</td>
<td></td>
<td>(1 ULB)</td>
<td></td>
<td>(1 DT)</td>
</tr>
<tr>
<td><strong>Readmission to RSCH (reason)</strong></td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>(1 SR, 1 DS)</td>
<td></td>
<td>(1 TKR, 1 BA)</td>
<td></td>
<td>(1 TKR, 1 BA)</td>
</tr>
<tr>
<td><strong>Other (reason)</strong></td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>(CaB)</td>
</tr>
</tbody>
</table>

Statistical comparisons between the S and NS groups, and between the S-C and NS-CP sub-groups:

* p<0.05,  ** p<0.01

(# Pneumonia) indicates the number of chest infections which developed into pneumonia.

**KEY:**
- SR: Surgical relocation of original prosthesis
- UT: Dislocation of original prosthesis, treated with traction
- ULB: Unstable prosthesis, leg brace fitted
- DS: Dislocated shoulder
- TKR: Total Knee Replacement operation performed
- BA: Broken ankle
- CaB: Cancer of the breast diagnosed
One patient in the NS group was diagnosed with cancer of the breast whilst in the acute hospital and died shortly after discharge to a MacMillan Unit.

None of the patients in the S-C sub-group experienced a fall during the total period of assessment, compared with two in the NS-CP sub-group. The infection rates were lower in the S-C sub-group, one patient had a UTI, one patient a chest infection and one patient a wound infection. In the NS-CP sub-group, two patients were diagnosed as having a UTI, 4 patients suffered a chest infection (of which one developed into pneumonia) (p < 0.05) and 3 patients had an infection in the wound. Pressure sores affected 9 patients in the NS-CP sub-group, compared with 3 patients in the S-C sub-group.

4.4.8.4 Mortality (Table 4.19)
The mortality observed over the six month period of study was higher in the NS group (20%), compared with the S group (9.5%), although this did not reach statistical significance. In the S group, one patient died (4.8%) during the initial stay in the acute hospital, and a further patient died between 8 weeks and 6 months, making a total of two (9.5%) during the total period of study. In contrast, no patients in the NS group died during the initial stay in the acute hospital, but two patients (9.5%) had died by 4 weeks post-discharge, a total of 3 patients (15%) were known to have died by 8 weeks post-discharge and 4 patients (20%) were known to have died by 6 months post-discharge. (One patient moved away from the area before the 8 week assessment and could not be located for follow up.)
Table 4.19

Mortality rates of the S and NS groups and the S-C and NS-CP sub-groups at each of the periods of assessment.

<table>
<thead>
<tr>
<th>Assessment time</th>
<th>S n=21</th>
<th>NS n=21</th>
<th>S-C n=13</th>
<th>NS-CP n=13</th>
</tr>
</thead>
<tbody>
<tr>
<td>During hospital</td>
<td>1/21 (4.8%)</td>
<td>0/21 (0%)</td>
<td>0/13 (0%)</td>
<td>0/13 (0%)</td>
</tr>
<tr>
<td>4 weeks post-discharge</td>
<td>1/21 (4.8%)</td>
<td>2/21 (9.5%)</td>
<td>0/13 (0%)</td>
<td>2/13 (15.4%) *</td>
</tr>
<tr>
<td>8 weeks post-discharge</td>
<td>1/21 (4.8%)</td>
<td>3/20 (15.0%) (1 = moved)</td>
<td>0/13 (0%) *</td>
<td>3/12 (25%) * (1 = moved)</td>
</tr>
<tr>
<td>6 months post-discharge</td>
<td>2/21 (9.6%)</td>
<td>4/20 (20%) (1 = moved)</td>
<td>0/13 (0%) *</td>
<td>4/12 (33.3%) * (1 = moved)</td>
</tr>
</tbody>
</table>

Results are presented as absolute numbers of patients died/total number of patients whose status is known (%).

Statistical comparisons between the S-C and NS-CP sub-groups: * p<0.05.
None of the patients in either the S-C group or the NS-CP group died during the initial stay in the acute hospital. No patients from the S-C group died at any time during the study period. In contrast, two patients (15.4%) in the NS-CP group had died by 4 weeks post-discharge ($p < 0.05$, compared with the S-C group); 3 patients were known to have died (25%) by 8 weeks post-discharge ($p < 0.05$, compared with S-C) and 4 patients (33.3%) by 6 months post-discharge ($p < 0.02$, compared with the S-C group).

The admission characteristics and baseline assessment results of those patients who died during the period of study are presented in Table 4.20.
### Table 4.20

Admission characteristics and baseline assessment values of patients who died during the period of study.

<table>
<thead>
<tr>
<th>Pt No</th>
<th>Sub Gp</th>
<th>Sur Type of surgery</th>
<th>Age</th>
<th>Sur NRS</th>
<th>Wt (kg)</th>
<th>TSF (mm)</th>
<th>TBP</th>
<th>MUAC (cm)</th>
<th>MUAMC (%)</th>
<th>Alb</th>
<th>RBP</th>
<th>vHGS (%)</th>
<th>MFT</th>
<th>Kcal</th>
<th>Prot (g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>17</td>
<td>S-NC</td>
<td>Em Emergency</td>
<td>17</td>
<td>42.7</td>
<td>22.2</td>
<td>20.1</td>
<td>40</td>
<td>34</td>
<td>&lt;1</td>
<td>74</td>
<td>0</td>
<td>611</td>
<td>1409</td>
<td>49.3</td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>S-NC</td>
<td>Em Emergency</td>
<td>12</td>
<td>69.2</td>
<td>10.9</td>
<td>294.8</td>
<td>43</td>
<td>30</td>
<td>&lt;1</td>
<td>74</td>
<td>0</td>
<td>611</td>
<td>1409</td>
<td>49.3</td>
<td></td>
</tr>
<tr>
<td>24</td>
<td>NS-CP</td>
<td>El Elective</td>
<td>15</td>
<td>6.4</td>
<td>21.1</td>
<td>19.1</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>1.5</td>
<td>39</td>
<td>290</td>
<td>7.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>27</td>
<td>NS-CP</td>
<td>El Elective</td>
<td>13</td>
<td>7.1</td>
<td>28.9</td>
<td>28.7</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>1.5</td>
<td>39</td>
<td>290</td>
<td>7.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>28</td>
<td>NS-CP</td>
<td>El Elective</td>
<td>14</td>
<td>6.9</td>
<td>22.0</td>
<td>19.8</td>
<td>53</td>
<td>51</td>
<td>1.3</td>
<td>98</td>
<td>411</td>
<td>868</td>
<td>27.9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>34</td>
<td>NS-CP</td>
<td>El Elective</td>
<td>13</td>
<td>81.5</td>
<td>12.9</td>
<td>34.0</td>
<td>31</td>
<td>81</td>
<td>4.0</td>
<td>87</td>
<td>868</td>
<td>27.9</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Admission characteristics and plasma protein assessment values:
4.4.9 Nutrient intake data

4.4.9.1 Nutritional intake from supplements

The median daily intake of the supplements consumed by each patient in the S-C sub-group is presented in Table 4.21 for the period of stay in the acute hospital and in Table 4.22 during the four weeks following discharge from the acute hospital.

Five of the 13 patients began to consume the supplements on the first day after surgery, a further two patients started on day 2, two patients on day 3 and one patient on day 4. Three patients were not able to tolerate the supplement until 5 days after surgery.

In most patients, there was a preference for one supplement in particular, which has been recorded as the principal supplement, with the volume recorded being the average of all the supplements consumed. In cases where a variety of supplements were chosen, with no predominant choice, the total amount of each supplement has been recorded. The average daily intake was calculated from the sum total, divided by the number of days for which the supplement was taken.

The most popular supplement chosen during the stay in the acute hospital was Fortimel, which was the sole or principal choice of 10 of the 13 patients. After discharge from hospital, Fortimel was again the most popular choice, being the sole choice of 5 patients and consumed in combination with others in a further 4 patients.
Table 4.21

Median daily intake of nutritional supplements consumed by each patient in the S-C sub-group, whilst in the acute hospital.

<table>
<thead>
<tr>
<th>Pt No/ Initials</th>
<th>Supp first consumed (days post-disch)</th>
<th>Principal supplement consumed</th>
<th>Volume (mls)</th>
<th>Energy (Kcals)</th>
<th>Protein (g)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>01 / ES</td>
<td>2</td>
<td>Fortimel</td>
<td>160 mls</td>
<td>160</td>
<td>14.6</td>
<td></td>
</tr>
<tr>
<td>02 / VC</td>
<td>5</td>
<td>Fortimel</td>
<td>205 mls</td>
<td>205</td>
<td>19.9</td>
<td></td>
</tr>
<tr>
<td>03 / LT</td>
<td>1</td>
<td>Enteral 250</td>
<td>250 mls</td>
<td>250</td>
<td>8.0</td>
<td></td>
</tr>
<tr>
<td>04 / KA</td>
<td>3</td>
<td>Liquisorb</td>
<td>325 mls</td>
<td>325</td>
<td>19.0</td>
<td></td>
</tr>
<tr>
<td>05 / MB</td>
<td>1</td>
<td>Fortimel</td>
<td>370 mls</td>
<td>370</td>
<td>35.9</td>
<td></td>
</tr>
<tr>
<td>06 / WL</td>
<td>4</td>
<td>Fortimel</td>
<td>200 mls</td>
<td>200</td>
<td>19.4</td>
<td></td>
</tr>
<tr>
<td>07 / IC</td>
<td>5</td>
<td>Fortimel</td>
<td>50 mls</td>
<td>50</td>
<td>4.9</td>
<td></td>
</tr>
<tr>
<td>08 / MR</td>
<td>1</td>
<td>Fortisip</td>
<td>160 mls</td>
<td>240</td>
<td>8.0</td>
<td></td>
</tr>
<tr>
<td>09 / MH</td>
<td>3</td>
<td>Fortimel</td>
<td>250 mls</td>
<td>250</td>
<td>24.3</td>
<td></td>
</tr>
<tr>
<td>10 / KB</td>
<td>5</td>
<td>Fortimel</td>
<td>160 mls</td>
<td>160</td>
<td>15.5</td>
<td></td>
</tr>
<tr>
<td>11 / MR</td>
<td>2</td>
<td>Fortimel</td>
<td>200 mls</td>
<td>200</td>
<td>19.4</td>
<td></td>
</tr>
<tr>
<td>12 / FE</td>
<td>1</td>
<td>Fortimel</td>
<td>250 mls</td>
<td>250</td>
<td>22.3</td>
<td></td>
</tr>
<tr>
<td>13 / GB</td>
<td>1</td>
<td>Fortimel</td>
<td>270 mls</td>
<td>270</td>
<td>26.2</td>
<td></td>
</tr>
<tr>
<td>Mean (sd)</td>
<td>2.6 (± 1.6)</td>
<td></td>
<td>217 mls (± 22)</td>
<td>223 kcal (± 20)</td>
<td>17.8 g (± 2.2)</td>
<td></td>
</tr>
<tr>
<td>Median (25th, 75th)</td>
<td>2.0 (1.0, 4.5)</td>
<td></td>
<td>205 mls (160, 260)</td>
<td>230 kcal (180, 260)</td>
<td>19.4 (10.5, 23.3)</td>
<td></td>
</tr>
</tbody>
</table>
Table 4.22

Median daily intake of nutritional supplements consumed by each patient in the S-C sub-group, during the four weeks following discharge from the acute hospital.

<table>
<thead>
<tr>
<th>Patient Initials</th>
<th>Principal Supplement</th>
<th>Volume (ml/d)</th>
<th>Weight (g)</th>
<th>Energy (Kcals)</th>
<th>Protein (g)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>21 / ES</td>
<td>Liquisorb</td>
<td>71 mls</td>
<td>71</td>
<td>2.9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>22 / VC</td>
<td>Protipud, Fortimel</td>
<td>100 mls</td>
<td>100</td>
<td>6.7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>23 / LT</td>
<td>Entera, Fortimel</td>
<td>20 mls</td>
<td>20</td>
<td>0.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>24 / EA</td>
<td>Fortimel</td>
<td>150 mls</td>
<td>150</td>
<td>5.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>25 / MB</td>
<td>Fortimel</td>
<td>310 mls</td>
<td>305</td>
<td>5.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>26 / WL</td>
<td>Fortimel</td>
<td>210 mls</td>
<td>205</td>
<td>5.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>27 / IC</td>
<td>Protipud, Fortimel</td>
<td>113 g</td>
<td>119.2</td>
<td>3.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>28 / MR</td>
<td>Protipud</td>
<td>150 g</td>
<td>150</td>
<td>5.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>29 / MH</td>
<td>Fortimel</td>
<td>400 mls</td>
<td>395</td>
<td>54.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30 / MR</td>
<td>Fortimel</td>
<td>200 mls</td>
<td>200</td>
<td>19.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>31 / PE</td>
<td>Fortimel</td>
<td>200 mls</td>
<td>200</td>
<td>19.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>32 / CH</td>
<td>Protipud, Fortimel</td>
<td>159 g</td>
<td>160</td>
<td>54.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td></td>
<td>248 mls</td>
<td>248</td>
<td>22.7 g</td>
<td>(4.185)</td>
<td></td>
</tr>
<tr>
<td>Median (25th, 75th)</td>
<td></td>
<td>250 mls</td>
<td>250</td>
<td>10.4 g</td>
<td>(9.5, 24.8)</td>
<td></td>
</tr>
</tbody>
</table>
The median volume consumed was 205 (160, 260) mls/g per day whilst in hospital and 200 (125, 390) mls/g per day during the post-discharge period. This corresponded to a median daily consumption of 230 (180, 260) Kcal and 19.4 (10.5, 24.3) g protein whilst in the acute hospital; followed by 280 (150, 370) Kcal and 19.4 (9.9, 34.9) g protein during the post discharge period.

Details of the supplements sampled by the S-NC sub group, and the reasons given for not wishing to continue are presented in Appendix IV, Table A4.2. Five of the eight patients not wishing to continue related their dislike of the supplements to the sweetness or richness of the supplement.

4.4.9.2 Nutritional intake from normal foods (24 hour dietary recalls)

From the 24 hour dietary recall data, the protein and energy intakes have been calculated for each of the patients at each of the time periods assessed. Results are expressed for the S and NS groups (Figures 4.14a and 4.15a, Tables 4.23a and 4.24a), for the S-C and NS-CP sub groups (Figures 4.14b and 4.15b, Tables 4.23b and 4.24b) and for the S-C and NS-NC sub groups (Figures 4.14c and 4.15c, Tables 4.23c and 4.24c).

The values for each individual patient are also presented in Appendix IV, Tables A4.3i to A4.iv.

Nutritional analysis of the 24 hour dietary recall data revealed no significant differences in the intakes of protein or energy from normal foods (excluding the supplement), between the S and NS groups at any of the time periods assessed (figures 4.14a and 4.15a). There was, however, a trend for the protein intakes to be lower in the NS, compared with the S, group. When the intakes of the S-C and NS-CP sub groups were compared,
the S-C group had a higher protein and energy intake (from normal foods) at the hospital and at the four week post discharge assessment (Figures 4.14b and 4.15b). These differences were statistically significant for the hospital assessment only for both protein (p < 0.01) and energy (p < 0.05).

The group who were offered the supplements but who did not consume them, the S-NC sub group, had lower intakes of protein and energy (from normal foods) than the S-C group at all the periods of assessment, with the exception of energy intake at four weeks post-discharge (Figures 4.14c and 4.15c). These differences were statistically significant for energy intake at the hospital assessment (p < 0.05) and the six month post-discharge assessment (p < 0.001), and for protein intake at the six month post-discharge assessment (p < 0.001).
Figure 4.14a. Daily protein intakes of the S and NS groups from normal foods (excluding the nutritional supplement), calculated from 24-hour dietary recall.

Results are represented as median values.

Table 4.23a. Daily protein intakes of the S and NS groups from normal foods (excluding the nutritional supplement), calculated from 24-hour dietary recall.

<table>
<thead>
<tr>
<th></th>
<th>Hospital</th>
<th>4 Weeks</th>
<th>6 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>S</td>
<td>Median</td>
<td>55.5</td>
<td>56.1</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>49.3</td>
<td>43.6</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>75.1</td>
<td>67.4</td>
</tr>
<tr>
<td>NS</td>
<td>Median</td>
<td>55.5</td>
<td>56.1</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>49.3</td>
<td>43.6</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>75.1</td>
<td>67.4</td>
</tr>
</tbody>
</table>

Statistical Significance: +

Results are presented as median values with 25th and 75th percentiles. Where 'n' refers to the number of patients.

Figure 4.15a. Daily energy intakes of the S and NS groups from normal foods (excluding the nutritional supplement), calculated from 24-hour dietary recall.

Results are represented as median values.

Table 4.24a. Daily energy intakes of the S and NS groups from normal foods (excluding the nutritional supplement), calculated from 24-hour dietary recall.

<table>
<thead>
<tr>
<th></th>
<th>Hospital</th>
<th>4 Weeks</th>
<th>6 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>S</td>
<td>Median</td>
<td>1,247</td>
<td>1,289</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>1,047</td>
<td>1,174</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>1,447</td>
<td>1,447</td>
</tr>
<tr>
<td>NS</td>
<td>Median</td>
<td>1,333</td>
<td>1,280</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>1,480</td>
<td>1,509</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>632</td>
<td>941</td>
</tr>
</tbody>
</table>

Statistical Significance: ns

Results are presented as median values with 25th and 75th percentiles. Where 'n' refers to the number of patients.
Table 4.23b Daily protein intakes of the S-C and NS-CP subgroups from normal foods (excluding the nutritional supplement), calculated from 24 hour dietary recall.

<table>
<thead>
<tr>
<th></th>
<th>Hospital</th>
<th>4 Weeks</th>
<th>6 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>S-C</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>63.3</td>
<td>62.5</td>
<td>61.3</td>
</tr>
<tr>
<td>25th percentile</td>
<td>52.6</td>
<td>40.4</td>
<td>52.2</td>
</tr>
<tr>
<td>75th percentile</td>
<td>72.7</td>
<td>69.0</td>
<td>63.7</td>
</tr>
<tr>
<td><strong>NS-CP</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>29.6</td>
<td>49.8</td>
<td>63.7</td>
</tr>
<tr>
<td>25th percentile</td>
<td>15.0</td>
<td>20.1</td>
<td>55.6</td>
</tr>
<tr>
<td>75th percentile</td>
<td>47.9</td>
<td>59.4</td>
<td>70.1</td>
</tr>
</tbody>
</table>

Results are presented as median values with 25th and 75th percentiles. Where 'n' refers to the number of patients. Values significantly different between groups ** P<0.01

Figure 4.14b Daily energy intakes of the S-C and NS-CP subgroups from normal foods (excluding the nutritional supplement), calculated from 24 hour dietary recall.

Results are represented as median values. Values significantly different between groups ** P<0.01

Table 4.24b Daily energy intakes of the S-C and NS-CP subgroups from normal foods (excluding the nutritional supplement), calculated from 24 hour dietary recall.

<table>
<thead>
<tr>
<th></th>
<th>Hospital</th>
<th>4 Weeks</th>
<th>6 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>S-C</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>1336</td>
<td>1273</td>
<td>1468</td>
</tr>
<tr>
<td>25th percentile</td>
<td>1241</td>
<td>1157</td>
<td>1287</td>
</tr>
<tr>
<td>75th percentile</td>
<td>1530</td>
<td>1671</td>
<td>1626</td>
</tr>
<tr>
<td><strong>NS-CP</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>868</td>
<td>1154</td>
<td>1450</td>
</tr>
<tr>
<td>25th percentile</td>
<td>411</td>
<td>739</td>
<td>932</td>
</tr>
<tr>
<td>75th percentile</td>
<td>1341</td>
<td>1320</td>
<td>1798</td>
</tr>
</tbody>
</table>

Results are presented as median values with 25th and 75th percentiles. Where 'n' refers to the number of patients. Values significantly different between groups * P<0.05
Figure 4.14c: Daily protein intakes of the S-C and S-NC groups from normal foods (excluding the nutritional supplement), calculated from 24 hour dietary recall.

Results are represented as median values.
Values significantly different between groups *** P<0.001.

Table 4.23c: Daily protein intakes of the S-C and S-NC subgroups from normal foods (excluding the nutritional supplement), calculated from 24 hour dietary recall.

<table>
<thead>
<tr>
<th></th>
<th>Hospital</th>
<th>4 Weeks</th>
<th>6 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>S-C</td>
<td>Median</td>
<td>63.3</td>
<td>62.5</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>52.6</td>
<td>40.4</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>72.7</td>
<td>69.0</td>
</tr>
<tr>
<td>n</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S-NC</td>
<td>Median</td>
<td>54.6</td>
<td>54.1</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>42.0</td>
<td>46.2</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>60.0</td>
<td>69.3</td>
</tr>
<tr>
<td>n</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Statistical Significance</td>
<td>ns</td>
<td>ns</td>
<td>***</td>
</tr>
</tbody>
</table>

Results are presented as median values with 25th and 75th percentiles. Where 'n' refers to the number of patients.
Values significantly different between groups *** P<0.001.

Figure 4.15c: Daily energy intakes of the S-C and S-NC subgroups from normal foods (excluding the nutritional supplement), calculated from 24 hour dietary recall.

Results are represented as median values.
Values significantly different between groups * P<0.05; *** P<0.001.

Table 4.24c: Daily energy intakes of the S-C and S-NC subgroups from normal foods (excluding the nutritional supplement), calculated from 24 hour dietary recall.

<table>
<thead>
<tr>
<th></th>
<th>Hospital</th>
<th>4 Weeks</th>
<th>6 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>S-C</td>
<td>Median</td>
<td>1336</td>
<td>1273</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>1241</td>
<td>1157</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>1530</td>
<td>1671</td>
</tr>
<tr>
<td>n</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S-NC</td>
<td>Median</td>
<td>1040</td>
<td>1302</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>924</td>
<td>1168</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>1256</td>
<td>1380</td>
</tr>
<tr>
<td>n</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Statistical Significance</td>
<td>*</td>
<td>ns</td>
<td>***</td>
</tr>
</tbody>
</table>

Results are presented as median values with 25th and 75th percentiles. Where 'n' refers to the number of patients.
Values significantly different between groups * P<0.05; *** P<0.001.
4.4.9.3 Nutritional intake from normal foods and nutritional supplement

When the nutritional value of the supplements consumed by each of the patients in the S-C sub group was included in the nutritional intake data, both protein (Figure 4.16, Table 4.25) and energy (Figure 4.17, Table 4.26) intakes were higher than those of either the NS-CP or the S-NC sub groups at the assessments performed during the period of supplementation. These differences were statistically significant when compared with the intakes of the NS-CP sub group at the hospital assessment [protein (p < 0.001), energy (p < 0.001)] and the four week post discharge assessment [(p < 0.001), energy (p < 0.05)]; and also when compared with the intakes of the S-NC sub group at the hospital assessment [protein (p < 0.01), energy (p < 0.001)] and the four week post discharge assessment [protein (p < 0.05), energy (p < 0.05)]. At the six month post discharge assessment, when the supplements were no longer being consumed, the S-NC sub group had significantly lower intakes of protein and energy than either the S-C sub group [protein (p < 0.001), energy (p < 0.001], and of protein compared with the NS-CP sub group (p < 0.001).
Figure 4.16  Total daily protein intakes of the four sub groups: S-C (including nutritional supplement), NS-CP, S-NC, and NS-CP.

Results are presented as median values.
Values significantly different from S-C group; * P<0.05, ** P<0.01, *** P<0.001, + P<0.06 close to statistical significance.

Table 4.25  Total daily protein intakes of the four sub groups: S-C (including nutritional supplement), NS-CP, S-NC, and NS-CP.

<table>
<thead>
<tr>
<th></th>
<th>Hospital</th>
<th>4 weeks</th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>S-C</td>
<td>Median</td>
<td>77.8</td>
<td>78.8</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>71.3</td>
<td>58.2</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>66.2</td>
<td>93.9</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>11</td>
<td>13</td>
</tr>
<tr>
<td>NS-CP</td>
<td>Median</td>
<td>29.6</td>
<td>49.8*</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>15.0</td>
<td>20.1</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>47.9</td>
<td>59.4</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>11</td>
<td>11</td>
</tr>
<tr>
<td>S-NC</td>
<td>Median</td>
<td>54.6</td>
<td>54.1</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>42.0</td>
<td>46.2</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>60.0</td>
<td>69.3</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>8</td>
<td>7</td>
</tr>
<tr>
<td>NS-NCP</td>
<td>Median</td>
<td>56.7</td>
<td>56.9</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>47.9</td>
<td>50.1</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>67.3</td>
<td>67.5</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>7</td>
<td>8</td>
</tr>
</tbody>
</table>

Results are presented as median values with 25th and 75th percentiles. 'n' refers to the number of patients.
Values significantly different from hospital value, within group comparisons * P<0.05; ** P<0.01.
Figure 4.17  Total daily energy intakes of the four sub groups: S-C (including nutritional supplement), NS-CP, S-NC, and NS-CP.

Results are presented as median values with the 25th and 75th percentiles represented by the bar.

Values significantly different from S-C group; * P<0.05, ** P<0.01, *** P<0.001, + P<0.06 close to statistical significance.

Table 4.26  Total daily energy intakes of the four sub groups: S-C (including nutritional supplement), NS-CP, S-NC, and NS-CP.

<table>
<thead>
<tr>
<th></th>
<th>Hospital</th>
<th>4 weeks</th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>S-C</td>
<td>Median</td>
<td>1549</td>
<td>1553</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>1360</td>
<td>1377</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>1770</td>
<td>2062</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>11</td>
<td>13</td>
</tr>
<tr>
<td>NS-CP</td>
<td>Median</td>
<td>868</td>
<td>1154 *</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>411</td>
<td>739</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>1341</td>
<td>1320</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>12</td>
<td>11</td>
</tr>
<tr>
<td>S-NC</td>
<td>Median</td>
<td>1040</td>
<td>1302</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>924</td>
<td>1168</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>1256</td>
<td>1380</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>8</td>
<td>7</td>
</tr>
<tr>
<td>NS-NCP</td>
<td>Median</td>
<td>1450</td>
<td>1438</td>
</tr>
<tr>
<td></td>
<td>25th percentile</td>
<td>1390</td>
<td>1272</td>
</tr>
<tr>
<td></td>
<td>75th percentile</td>
<td>1584</td>
<td>1558</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>7</td>
<td>8</td>
</tr>
</tbody>
</table>

Results are presented as median values with 25th and 75th percentiles. 'n' refers to the number of patients.

Values significantly different from hospital value, within group comparisons * P<0.05; ** P<0.01.
4.4.9.4 Comparison of protein and energy intakes with the Department of Health (1991) current recommendations

The current DHSS recommendations for energy and protein intakes in the elderly are given in Table 4.27. The number (%) of patients in each of the sub groups whose daily intake of protein or energy, from normal foods, was less than the current recommendations (Department of Health, 1991) are given in Tables 4.28 and 4.29, respectively, for each of the time periods assessed.

At the hospital assessment, 3/19 (16%) of the S group and 9/18 (50%) of the NS group consumed less than 46.5 g protein/day, as currently recommended by the Department of Health (1991). Four weeks into the discharge period, these figures were 6/20 (30%) for the S group and 5/19 (26%) for the NS group; by six months post discharge the numbers were 6/18 (33%) in the S group and 3/13 (23%) in the NS group.

The current recommendations for average daily energy intake of 1900 kcal for females aged 65-74 years and 1810 kcal for females aged 75 years and over, was not achieved by any of the patients at the hospital assessment. Four weeks after discharge, 17/20 (85%) of the S group and 18/19 (95%) of the NS group did not reach this level of intake; by six months the numbers were 17/17 (100%) for the S group and 10/11 (91%) of the NS group.

When the intakes of the S-C sub group were compared with the intakes of the NS-CP sub group, the numbers of patients not meeting the RNI for protein at the hospital assessment were 1/11 (9%) in the S-C group and 8/11 (73%) in the NS-CP group. Four weeks after discharge these figures were 4/13 (31%) of the S-C group and 5/11 (45%) of the NS-CP group. At the six month follow up, 1/12 (8%) of the S-C patients and 1/7 (14%) of the NS-CP group did not meet this level of protein intake. The number of patients not
meeting the EAR of energy in the S-C group was 11/11 (100%) in hospital, 10/13 (77%) at four weeks and 11/11 (100%) at six months. In the NS-CP group the corresponding figures were 11/11 (100%) in hospital, 10/11 (91%) at four weeks and 6/7 (86%) at six months post discharge.

When the nutritional value of the supplements was added to the nutrient intake from normal foods, all patients in the S-C group met the RNI for protein, but 9/11 (82%) failed to meet the EAR for energy, at the hospital assessment (Table 4.30). At four weeks post discharge, 2/13 (15%) of the S-C group did not meet their RNI for protein and 10/13 (77%) did not meet the EAR for energy.
<table>
<thead>
<tr>
<th>Reference Nutrient Intake (RNI) Protein (g/day)</th>
<th>Estimated Average Daily Requirement (EAR) Energy (kcals)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Females 50 years and over 46.5</td>
<td>Females 65-74 years 1900</td>
</tr>
<tr>
<td></td>
<td>Females 75 years and over 1810</td>
</tr>
</tbody>
</table>
Table 4.28
Numbers (%) of patients whose daily intake of protein from normal foods (calculated from 24 hour dietary recall) was less than the Department of Health (1991) recommendations.

<table>
<thead>
<tr>
<th>Sub group</th>
<th>Hospital</th>
<th>4 weeks PD</th>
<th>6 months PD</th>
</tr>
</thead>
<tbody>
<tr>
<td>S-C</td>
<td>1/11 (9%)</td>
<td>4/13 (31%)</td>
<td>1/12 (8%)</td>
</tr>
<tr>
<td>S-NC</td>
<td>2/8 (25%)</td>
<td>2/7 (29%)</td>
<td>5/6 (83%)</td>
</tr>
<tr>
<td>NS-CP</td>
<td>8/11 (73%)</td>
<td>5/11 (45%)</td>
<td>1/7 (14%)</td>
</tr>
<tr>
<td>NS-NCP</td>
<td>1/7 (14%)</td>
<td>0/8 (0%)</td>
<td>2/6 (33%)</td>
</tr>
</tbody>
</table>

Table 4.29
Numbers (%) of patients whose daily intake of energy from normal foods (calculated from 24 hour dietary recall) was less than the Department of Health (1991) recommendations.

<table>
<thead>
<tr>
<th>Sub group</th>
<th>Hospital</th>
<th>4 weeks PD</th>
<th>6 months PD</th>
</tr>
</thead>
<tbody>
<tr>
<td>S-C</td>
<td>11/11 (100%)</td>
<td>10/13 (77%)</td>
<td>11/11 (100%)</td>
</tr>
<tr>
<td>S-NC</td>
<td>8/8 (100%)</td>
<td>7/7 (100%)</td>
<td>6/6 (100%)</td>
</tr>
<tr>
<td>NS-CP</td>
<td>11/11 (100%)</td>
<td>10/11 (91%)</td>
<td>6/7 (86%)</td>
</tr>
<tr>
<td>NS-NCP</td>
<td>7/7 (100%)</td>
<td>8/8 (100%)</td>
<td>4/6 (67%)</td>
</tr>
</tbody>
</table>

Table 4.30
Number (%) of patients whose daily intake of protein or energy (normal foods and supplement) was less than the Department of Health (1991) recommendations.

<table>
<thead>
<tr>
<th>S-C sub-group</th>
<th>Number (%) patients, total daily protein intake &lt; RNI</th>
<th>Number (%) patients total daily energy intake &lt; EAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital</td>
<td>0/11 (0%)</td>
<td>9/11 (62%)</td>
</tr>
<tr>
<td>Four weeks post-discharge</td>
<td>2/13 (15%)</td>
<td>10/13 (77%)</td>
</tr>
</tbody>
</table>
4.5 DISCUSSION

The results which have been presented in the previous section (4.4) have encompassed a spectrum of anthropometric, biochemical and clinical data. The major findings will be summarised before proceeding with their discussion, with particular consideration being given to the original aims of the study. Attention will be focused on the outcomes of the sub group who consumed the supplements (S-C) with their admission pairs from the group which were not offered the supplement (NS-CP).

The aim of the study design was to provide nutritional support to a group of patients regarded as being "nutritionally vulnerable" throughout the period when it was likely to have the greatest impact on improving morbidity, and then to evaluate the impact of this nutritional support in both the short and long term. The time period over which the supplements were offered was during the stay in, and for four weeks after discharge from, the acute hospital. During this period, the data obtained from the NS ("control") group suggested that a decline in total body weight, particularly muscle stores (assessed by MUAC and MUAMC), would be the natural course followed by this patient population if no nutritional intervention was attempted. For some parameters, the decline continued beyond the eight week assessment. Serum protein determinations indicated that the trauma was associated with a decline in serum albumin from admission to discharge, whether the supplements were consumed or not. However, return to normal values was more marked in supplemented patients. In addition, the retinol binding protein determinations indicated that the provision of nutritional supplements led to an accelerated improvement in serum protein status following discharge and resulted in the six month post discharge values being significantly higher than the admission value. This suggests that improvements in protein status are not only sustained, but continue long after the supplement has ceased to be provided. The changes
observed in functional muscle status (assessed by HGS) were similar in the S and NS groups, although it was only the S-C group in whom a significant improvement was noted by the eight week post discharge assessment. These observations support the period of supplementation chosen, although it could be argued that nutritional support should have been extended to eight weeks post discharge from the acute hospital. When interpreting these results, it should be remembered that, with the exception of certain anthropometric variables (body weight, MUAC and MUAMC), the median values of the S and NS groups were not significantly different at the start of the study.

Perhaps of most clinical and economic relevance was that 10 patients in the NS-CP group required a further period of convalescence time in hospital compared with only 5 in the S-C sub group. The duration of convalescence required was significantly less in the S-C group compared with the NS-CP group. These differences indicate that the patients receiving the supplements experienced a faster, more progressive recovery towards a relatively independent lifestyle. This was reinforced by the observation that 92% of the S-C group had been sufficiently independent to return to their pre-admission way of living by eight weeks after discharge from the acute hospital, compared with only 46% of the patients in the NS-CP group. The Visick independence of mobility scores again support the view that the S-C group achieved a higher degree of independence in a faster time and it was not until the six month assessment that the differences were no longer statistically significant. Also of clinical relevance were the lower infection and other complication rates observed in the S-C group and the lower mortality observed in the S-C sub group over the period of study. The observed mortality rate of 20% in the NS group was similar to that reported by other workers (Refer to section 4.1), but was less than half of this.
"expected" rate in the S group as a whole and no deaths were observed in the sub group who consumed the supplements offered (S-C).

The rate of compliance to the supplement regimen was somewhat less than was anticipated, being 62%, despite considerable efforts being made to accommodate a variety of preferences for flavour and texture. Attempts to identify any characteristics of non-compliant patients, revealed that the group were older and comprised a higher proportion of patients admitted for emergency surgery for repair of a hip fracture. However, as these two factors are closely related (the incidence of hip fractures increasing with advancing age) it was not possible to separate these factors. No other factors were identified, but clearly, if the benefits of the supplements are to be maximised, further attempts to improve compliance must be made.

The concern that the provision of nutritional supplements would suppress appetite and result in a reduction in nutrient intake from normal foods did not appear to be a problem, indicated by the observation that the energy and protein intakes of the S group were not less than those of the NS group. The data supported a fundamental criterion of the study that the supplements should serve as a supplement to normal foods, not a replacement. The reported dietary intakes of the S-C sub group suggested that intake of normal foods may actually be increased in those who consume the supplements, the supplements thereby acting as an appetite stimulant, although the limitations of the 24 hour recall method of dietary intake assessment must be recognised. In order to investigate this further, a more rigorous method of assessment of dietary intake would need to be employed.

Many of the statistical differences observed when comparisons were made between the S-C and NS-CP sub groups (ie., per protocol analysis) were
also observed when comparisons were made between the S and NS groups (i.e., intention to treat analysis). This was observed for body weight, MUAC, MUAMC, albumin, RBP. For other data, the difference was only statistically significant when comparisons were made using the per protocol analysis (e.g., mortality). In general, this gives an indication as to the degree of impact of the supplements. The results will now be discussed in more detail and for clarity will be divided into the following sub headings:

4.5.1 Recruitment and compliance rates.
4.5.2 Admission characteristics and baseline measurements.
4.5.3 Changes in anthropometric and biochemical indices over the period of study.
4.5.4 Changes in functional indices over the period of study.
4.5.5 Clinical outcome.
4.5.6 Dietary intakes.

4.5.1 Recruitment and compliance rates
In view of the experience gained from the feasibility study, it was anticipated that over an 18 month period, approximately 16-20 patients who were recruited into the follow-up study, would comply to the supplement regimen as requested. In reality, only 13 patients comprised the S-C sub group. In the original plan, it was recognised that the investigator would not be able to recruit patients on a continuous basis, due to the increased work load from the post-discharge follow-up assessments. The time required to conduct these assessments however was underestimated. Due to the timing of the visits and the distance travelled, it was usually only possible to visit one patient each afternoon. In addition to this, several weeks were spent in the laboratory establishing the methodology for the determination of serum albumin and retinol binding protein. For these reasons, recruitment took place intermittently, from January - July 1988
and then from January - July 1989, during which time 73 patients underwent detailed structured interviews. The proportion of patients classified as "High Risk" (HR) was similar to the anticipated figure, giving rise to a study population of 42 patients.

The categorisation of patients into "High" and "Low" risk groups was achieved by means of the Nutrition Risk Questionnaire (NRQ) giving a Nutrition Risk Score (NRS). The distribution of the NRS shows two distinct peaks, one peak at 5.0 and the second peak at 11.0. In between these two peaks, was a trough NRS of 7.5. This suggests that there are two distinct groups of patients and that the cut-off score of $\geq 8.0$ was the correct value to use to divide the two groups. The observation that the LR group comprised 64.5% of patients admitted for elective hip surgery (total hip replacement), compared with only 33.5% in the HR group, suggests that patients admitted for elective surgery are less likely to be nutritionally compromised than those who are admitted for emergency surgery (fractured femur). The fact that the LR group are younger and that age is included in the NRS, must not be overlooked. However, this observation is supported by a study of 129 patients undergoing orthopaedic procedures (Jensen et al., 1982) in which the lowest incidence of nutritional depletion was identified in patients undergoing total hip replacement surgery. The validity of the NRQ as a means of identifying "High Risk" patients has not been tested as part of the present study, although it has shown to be of value (along with other objective indices of nutritional status) in discriminating patients who do less well clinically (Lumbers, 1993). Its use in the present study was deemed to be appropriate since it provided a simple and quick method of identifying patients for recruitment into the supplement study. It is, however, accepted that its discriminating power needs further investigation before it could be recommended for routine use in the clinical setting.
Of the 21 who were alternately allocated to receive the supplements, 13 (62%) were regarded as compliant to the regimen. The compliance rate in this current study was, therefore, similar to that of the feasibility study (61%) despite subjects in the current study being offered a range of supplements with different flavours and mouth feel. Clearly, compliance appears to be influenced by factors other than just variety of choice. It could be argued that all the supplements offered were of a similar nature, that is, sweet and generally milk-based. (One patient, 03/LT, did consume Lemon & Lime flavoured Enteral 250, but this was only included in the range after a special request.) Of those patients who tried the supplements but who did not wish to continue, the most common reasons given for discontinuation reflected the dislike of the sweet, rich, creaminess of the drinks. Even the patients who did comply asked whether there was a savoury choice available, suggesting that for them too, the sweet choice may not be the most preferred option. Undoubtedly, the reason that most commercially available supplements are milk-based, is that milk provides a well balanced nutritional medium into which additional energy, protein and concentrated nutrients can be added, whilst leaving the characteristics of the original product relatively unchanged. It is also interesting to note that the "Non-Compliant" (S-NC) sub-group were older than the "Compliant" (S-C) sub-group, although this difference did not reach statistical significance, and a higher proportion of the S-NC group were emergency admissions following accidental fracture to the femur. As already mentioned, the difference in fracture rates is almost certainly accounted for by the higher age distribution of the patients in this group, almost 60% of the hip fractures occurring in women over the age of 75 years. However, since nine of the thirteen patients who did comply to the supplement regimen were also aged 75 years or over, there must be factors other than age which influence whether a patient consumes the supplement which is offered. The attitude of the patient seemed to play an important
role. Although no objective data were documented to support this, the investigator's perception was that the patients who did comply to the regimen either: (1) recognised that they may not be meeting their nutritional requirements by the ingestion of normal foods, particularly at a time when they believed their needs may be increased or, (2) thought that additional nutrients would be of benefit at this time. In contrast to this, the attitude of the patients in the S-NC group seemed to be either: (1) that they were obtaining sufficient nutrients from normal foods or, (2) that nutritional intake was not an important factor in their recovery. If these impressions are accurate and representative of the patient group as a whole, then it suggests there may be a role for the nutritional education of patients. Further investigation of patient "attitude" and the influence of patient nutrition education on compliance rates to nutritional supplements will be explored in Chapter 5.

Poor compliance has been reported as a problem by other workers. In the large supplement study in geriatric patients (Larsson et al., 1990) 39 (19.8%) of the 197 patients offered the supplement refused to consume it. A weakness of this study was that the proportion of supplement which was consumed by the remaining 80.2% was not reported. In the study of Delmi et al (1990), the elderly fractured neck of femur patients (male and female) were reported to have "completely ingested" a nutritional supplement containing 254 kcal and 20 g protein in 250 mls each day, yet earlier workers had reported "poor tolerance" to a supplement containing 18.5 g protein and 320 kcal in a similar group of elderly women with femoral fractures (Stableforth, 1986). This difference in reported compliance rates in two similar patient populations may be due to differences in methods of assessment, or it could suggest that poor compliance in females is more of a problem than in males.
4.5.2 Admission characteristics and baseline measurements
The admission characteristics of the patients recruited into this current study were similar to those recruited into the feasibility study (Chapter 3) with respect to age and NRS. There was a larger proportion of emergency admission, for repair of a fractured femur in the feasibility study, but as already mentioned in Chapter 3, this probably reflected the fact that recruitment took place from December to May including the winter months when the incidence of fractured femur admissions in Britain is highest. This peak incidence has been shown to occur in thin individuals, whose falls most frequently occurred indoors, and were more likely to be hypothermic on admission to hospital. In contrast, normally nourished patients were more likely to be normothermic and experience their accidents out of doors (Bastow et al., 1983b). These observations have led to the hypothesis that chronic undernutrition might be associated with the defects of thermoregulation predisposing to hypothermia in cold weather.

The only notable difference in admission values between the two study populations, of the current and the feasibility (Chapter 3) studies, was that the S group of the feasibility study had a higher admission TSF value than that of the NS group (not significant), whereas in the current study, the S group had a lower admission TSF value than that of the NS group (non-significant). When the mean admission TSF value of the S group in the current study was compared with the mean admission value of the S group in the feasibility study, the values were significantly different ($p < 0.01$). This implies that the S group of the current study had significantly less fat stores on admission than the S group of the feasibility study and could, therefore, have responded differently to the provision of supplements. Small differences in some parameters would be expected when observing two groups of patients, but for the purpose of study, the patients recruited into the feasibility study and the current study can be regarded as
originating from a similar patient population. Comparison of the mean (±sd) admission values of serum albumin and anthropometric measurements between the patients in the S and NS groups of the current study, with those of the S and NS groups of the feasibility study, indicate that the two study populations comprised patients with a similar nutritional status.

In the current study, there were no significant differences in the results of routine haematological tests, including parameters of haemoglobin (Hb), white cell count (WCC) or platelets, or serum creatinine values, between the S and NS groups on admission, and all group median values were within the normal ranges. This indicates that the group as a whole showed no clinical signs of iron deficient anaemia, infection, folate deficiency or renal impairment. The 25th and 75th percentiles were also within normal range for haemoglobin, WCC and platelets. However, the 25th percentile for creatinine was below the normal range, indicating that at least 25% of the patients in the groups had a sub-normal creatinine value. This is regarded as being of no clinical significance, possibly reflecting the low muscle mass which is expected in the elderly. Indeed many hospital laboratory normal ranges do not quote a lower limit of normal. Interestingly, the haemoglobin values of this group of patients were very similar to both the "well nourished" and "thin" groups of patients described by Bastow and colleagues in the nasogastric feeding study of female patients with a fractured femur (1983a). In this study, the group who were described as well nourished had a mean haemoglobin value of 12.6 g/dl and the thin group had a mean value of 12.1 g/dl, similar to the median value of 12.3 g/dl found in both the S and NS groups in the current study. However, it might have been expected that the S and NS groups would have had values more like those of the "very thin" group in the Bastow study, the mean of which was 10.1 g/dl.
Nutritional assessment measurements have been performed on a group of 65 young and 44 elderly hospitalised subjects with protein-calorie malnutrition and the values compared to the measurements of 40 healthy free-living young and 40 elderly males and females (Mitchell and Lipschitz, 1982). The study revealed that iron deficient anaemia was usually evident in young subjects with malnutrition, but only distinguished the well nourished elderly from malnourished elderly if a lower limit of normal for haemoglobin was used (12 g/dl for males and 10 g/dl for females). Thus the use of haemoglobin as a measure of malnutrition in the elderly is questionable.

The creatinine values reported in the current study were similar to those observed in female patients admitted for long term geriatric care (Elmståhl and Steen, 1987) in which the mean value was 88 mmol/l. Serum creatinine is not a useful indicator of nutritional status, but urinary creatinine excretion, expressed as an index of height (Creatinine Height Index, CHI) has been found to be a good predictor of reductions in lean body mass in malnourished young males (Mitchell and Lipschitz, 1982), but of less value in young females. The use of the CHI was not considered for the current study because of practical difficulties involved in obtaining 24 hour urine collections and measuring height accurately in the elderly.

It was observed that the group of patients in the S group of the current study had significantly lower baseline values for body weight, MUAC and MUAMC than that of the NS group. This indicates that the S group were in a more compromised nutritional state than the NS group at the start of the study. The fact that the difference in TSF was not statistically significant suggests that their protein stores were more compromised than their fat stores. If this was the case, it would be expected that the serum albumin and retinol binding protein (RBP) would also be different between
the two groups. The significantly lower RBP of the S group suggests that the recent intake of protein was indeed low. There was, however, no significant difference in the serum albumin between the two groups, suggesting that the long term protein intake of the S group was not necessarily lower than that of the NS group. Although these two results seem to be conflicting, the observation that both groups have serum albumin values at the lower end of the normal range could suggest that the current intakes of protein are low in both groups, but that there has been a metabolic adaptation to the regular low intake.

In a recent observational study (Mansell et al., 1990) the recognition of low anthropometric indices in elderly females with fractured neck of femur has been well documented. This detailed assessment included measurements in 470 elderly (age 77.3 ± (SE) 0.32, range 59-103 years) female patients admitted to hospital with fracture of the femur (FNF); 103 healthy, mobile, elderly (age 72.5 ± 0.48 years, range 65-89 years) female subjects; and 90 unselected general medical and surgical female patients (age 79.1 ± 0.78, range 65-99 years). The study demonstrated quite clearly that there were very considerable differences in the anthropometric values of the three groups. Mean TSF was 13.0 ± 0.59 mm in the FNF group compared with 24.7 ± 0.70 mm in the healthy subjects (p < 0.001). (Unfortunately, no data was presented for the TSF of the geriatric in-patients.) Mean MUAC in the FNF group was 22.8 ± 0.21 cm compared with 25.9 ± 0.41 cm in the geriatric in-patients and with 28.6 ± 0.27 cm in the group of healthy subjects (p < 0.001 for all comparisons). Although in the current study the TSF values were slightly lower and the MUAC values were slightly higher than those reported by Mansell et al., the values were similar. Patients in the current study were older than those studied by Mansell et al. and this may account for the lower TSF in patients reported here. From the observational study (Mansell et al., 1990) it was noted that there was a
significant fall in TSF with age in the fracture group (p< 0.001) equivalent to a rate of decline of -0.16 ± 0.03 mm/yr. A smaller study evaluating the relationship between nutritional status and complications in patients with hip fracture, included the assessment of the TSF of 27 female patients admitted to hospital (Mean age 77.7, range 53-93 years). The mean TSF of 22 patients in this group was 15.8 ± 9.3 sd, higher than the values found in the HR group of the current study. It should be remembered that of the 73 patients initially interviewed, 31 of them were categorised as "Low Risk" by the NRQ, and were therefore not followed further within the framework of the current study reported here. The purpose of the NRQ was to identify individuals likely to be nutritionally compromised. It is, therefore not unexpected that the HR group had a lower TSF than reported in similar studies which have not first identified those patients likely to be nutritionally compromised. The TSF results observed in the current study suggest that the patients in the HR group were compromised in terms of body fat stores, but MUAC data indicated that the body protein stores were not so severely depleted. Anthropometric values reported in geriatric patients admitted for long term care (Elmstäthl and Steen, 1987) have been reported as similar to those observed in the current study, mean TSF being 11.0 mm and mean MUAC being 23.3 cm.

Low-normal serum albumin values reported on admission to hospital in this study, have also been reported in other studies. In a similar group of 53 women and 13 men (mean age 73, range 53-98 years) admitted to hospital with a fractured hip (Patterson et al., 1992), the mean serum albumin values were reported to be 36 ± 5 g/l for those patients who later developed complications and 37 ± 5 g/l for those who did not develop complications and are comparable with those found in patients in the current study. Even lower values have been reported in a prospective assessment of nutritional status and complications in patients with fractures of the hip (Foster et al.,
1990) when seven men and 33 women (mean age 78.2, range 45-97 years) were followed for up to 11 months after surgery. The patients who died during the follow-up period had an initial albumin of 28.2 g/l compared with 34.6 g/l in those who were survivors. The admission serum albumin values of the patients who died during the current study were not as low as previously reported, with the lowest value being 31.0 g/l, although three of the four available values were below 45 g/l. The values reported in the current study were similar to those observed in 18 elderly nursing home residents (Harrill et al., 1981) whose food intake was judged as being less than adequate by nursing staff. These patients had mean serum albumin measurements of 38 g/dl, similar to the serum albumins in patients in the current study, which suggests that the patients in the current study also had a less than adequate food intake prior to admission to hospital. The slightly higher mean serum albumin value of 39.0 g/l reported in patients admitted to hospital for total hip replacement (Jensen et al., 1982) again reinforces the suggestion that this group of patients were in a less compromised nutritional state prior to admission. It could also be argued that this may have been expected as the patients in the Jensen study were younger (mean age 51, range 17-78 years). Regardless of age, of all the nutritional assessments performed in the observational study of healthy and malnourished patients (Mitchell and Lipschitz, 1982), serum albumin was found to be the best predictor of malnutrition. In both young and old healthy subjects, a value below 40 g/l was unusual and no overlap occurred between the well nourished and malnourished groups. Interestingly, the mean (± SEM) serum albumin value of the 44 elderly malnourished patients was 26 (± 0.1) g/l compared with a value of 41 (± 0.1) g/l in the 40 well nourished elderly (p < 0.01). Serum albumin may also be a good predictor of functional recovery. In a study which investigated whether social support had an influence on the recovery of function among patients who had sustained a hip fracture, serum albumin was a better predictor of
subsequent functional recovery six months after discharge, than anthropometric measurements of nutritional status, or the number or severity of coexisting illnesses (Cummings et al., 1988).

It should be remembered that factors other than nutritional intake can influence serum albumin results. In some groups, acute illness seems to be a more important determinant of serum albumin and prealbumin than dietary deficiency (Freidman et al., 1985) and with any long term study, the possible effect of any seasonal variation should be considered. The seasonal variation in serum albumin has been documented in both elderly women and men (Reilly et al., 1987), but in the 160 institutionalised subjects studied in a Romanian hospital, the difference was statistically significant in the women only, showing a trough in the Spring and highest values in the Winter. Although the actual figures were not presented in this paper, reading from the graphs, the mean Spring value was approximately 37.2 g/l and the Winter value approximately 38.4 g/l, both higher than the values measured in the current study. These results contrast with those found in 2000 English male workers (Gidlow et al., 1983), in whom a peak serum albumin was noted in February and a trough in December. However, these subjects were taken from an active work force and were, therefore, likely to be much younger.

Despite the apparent differences in protein status at baseline, (assessed by anthropometric and biochemical measures) there were no significant differences in muscle function as assessed by voluntary hand grip strength (vHGS). The fact that this assessment relies on the "voluntary" grip exerted by the patient does mean that many other factors, such as mood, pain, concentration, apprehension and environment, will influence the force exerted. In addition to these subjective factors, it is likely that a large proportion of this group of patients will be suffering restriction in joint
movement, and thus grip, due to osteoarthritis or rheumatoid arthritis. All of these factors will have affected each patient's grip strength to a lesser or greater extent. These over-riding influences indicate that grip strength is not an accurate measure of nutritional status. In a recent study of 1042 individuals aged 65 years and over living in the Nottinghamshire community, hand grip strength in the dominant hand was reported as one of the most influential in predicting reports of recent falls (Blake et al., 1988). This was supported by another British study of 983 randomly selected people aged 65 years and over, in which those who had fallen one or more times in the past had a reduced grip strength (Wickham et al., 1989). A study of two groups of 92 elderly subjects (mean age 77 years, range 65-89) living in South London, in which one group attended a local day centre (a socially orientated establishment) and the other a local day hospital (therapeutically orientated), revealed that the two groups had similar nutritional intakes and biochemical indices. However, there were significant differences in body weight, TSF, MUAC, in functional status (assessed by questionnaires) and muscle strength (biceps, quadriceps and voluntary hand grip strength), in favour of the day centre group (Mowat et al., 1992). From these results, the authors concluded that the anthropometric indices, rather than nutrient intake or biochemical measures, were the most reliable markers of disease and disability. Comparing the anthropometric values of the women in these two groups with the values from the current study, the anthropometric measurements of the 26 women attending the day hospital were similar to those of the current study (mean values ± sd: weight 57.1 ± 12.2 kg, TSF 14.0 ± 6.8 mm, MUAC 26.8 ± 3.9 cm, MUAMC 26.3 ± 3.8 cm). In contrast, the anthropometric measures of the 13 women attending the day centre were higher (mean values ± sd: weight 68.1 ± 11.4 kg, TSF 21.7 ± 5.6 mm, MUAC 30.3 ± 5.6 cm, MUAMC 29.7 cm). In the study by Mowat et al, muscle strength for biceps (elbow flexion), quadriceps (knee extension) and
hand grip strength (hand held dynamometer) were less in the women who attended the day hospital, compared with those who attended the day centre, and differences were statistically significant in all cases except for the vHGS measurement in the women. In conclusion, the authors stated that no consistent relationship was found between nutritional intake and muscle strength. Further work which suggests that calf and biceps muscle strength may be more valuable than vHGS is that of Pearson et al (1985) in which calf and muscle were chosen as the appropriate muscles in which to measure the strength of 184 independently living subjects aged 65-90 years from an urban practice in Nottinghamshire. This group were regarded as well nourished (mean ± SEM body weight of females 65 ± 0.9 kg, TSF 24.6 ± 0.65 mm) but it is noted that there was a highly significant correlation between functional strength and muscle area for both arm (r=0.78) and calf (r=0.68) and that arm and calf strength were highly significantly correlated (r=0.68) as were arm and calf areas (r=0.72). These studies suggest that vHGS, as used in the current study, may not have been the best choice of method for discriminating the effects of nutrition on muscle function.

With regards to mental function, all patients scored highly on the initial assessment and the test employed was likely to be not sufficiently discriminatory.

The significant differences in body weight, MUAC, MUAMC and RBP noted between the S and NS groups are also apparent between the S-C and NS-CP sub-groups, with only the differences in TSF not being statistically significant.

It is recognised that such differences, present at the start of the study, imply that the group who were offered the nutritional supplements were in
a more compromised nutritional state than the group who were not offered the supplements. Therefore, the two groups were different at the start of the study such that the NS group was not a "matched control group" for the S group. The same applies to comparisons of outcome made between the S-C and NS-CP sub groups. It could be suggested that compassionate observer bias may have been responsible for the differences, by categorising the patients who appeared to be more in need of the supplements into the group which ensured that they would be offered them. However, even if this had been a conscious decision, it would have been difficult to instigate because of the systematic alternate allocation of patients into the S and NS groups, albeit even with the modification to this system that was employed during the study. In retrospect, this deviation from the allocation system should not have been made as it may have introduced bias. The differences in the nutritional status of the two groups of patients at the initial assessment may partly be explained by possible bias in selection, but it is likely to be an effect of studying a relatively small number of patients. If greater resources had been available, it would have been preferable to stratify the patients in the two groups, and pair match them with respect to age and body mass index (BMI).

4.5.3 Changes in anthropometric and biochemical indices over the period of study.

In the current study, a gradual increase in body weight was noted in the S and S-C groups, compared with the NS and NS-CP groups who demonstrated a significant decline in body weight from hospital to 8 weeks post discharge. This suggests that the provision of supplements prevented the loss of body tissue which would have otherwise occurred. However, it could be argued that, because of the initial difference in weight between the two groups, the NS-CP group had a greater nutritional intake prior to admission and therefore had more tissue reserves to utilise. In contrast,
the S-C group may have had a lower nutritional intake for some time before admission to hospital and may have reduced their metabolism to adapt to this lower intake. Then upon receiving a higher nutritional intake, the nutrients may have been utilised more efficiently. However, this suggestion is not supported by the dietary intake data throughout the period of study.

The results of the anthropometric measurement showed that there were no significant changes in the body fat reserves (as assessed by TSF) in any of the groups. However, the decline in MUAC and MAUMC observed in the NS and NS-CP groups, but not in the S and S-C groups, indicates that the provision of nutritional supplements prevented the losses which would have otherwise occurred. These differences were most noticeable up until the eight week post discharge assessment. It was not until between the eight weeks and six month assessment, that body weight started to increase again in the NS and NS-CP groups. This indicates that body stores were taking longer to be replenished in the groups not receiving the supplements. The MAUC and MUAMC results demonstrated that muscle protein reserves were still not replenished to their admission values in the groups not receiving or not consuming the supplements, whereas the group who did consume the supplements had been able to maintain their protein stores even though the supplements were no longer offered. Anthropometry makes the assumption that changes occurring in the arm reflect changes occurring in the rest of the body. To determine the changes occurring in specific regions of the body a method such as Dual X-ray Absorptiometry (DEXA) could have been employed, however, the cost and practicalities of this method were not appropriate for this study. Leucine turnover studies would also provide valuable information regarding protein synthesis and turnover in this group of patients.
The serum albumin results obtained in the current study suggest that both groups suffered a deterioration in protein status from admission to discharge, followed by a recovery in both groups but at different rates. The changes in albumin in the NS-CP group suggested that there was a gradual deterioration from admission until at least 4 weeks after discharge but, by the 6 months' assessment, the baseline values had almost been regained. The significant increase in serum albumin of the S-C group observed from admission to the end of the period of supplementation suggested that the provision of supplements improved the serum protein status. The serum albumin and MUAC results suggested that by 6 months post-discharge, the protein status of the NS-CP group was returning towards the pre-surgery value, but that the muscle tissue was slower to respond to change.

Serum RBP has a shorter half life (2 days) than albumin (18-20 days) and is therefore more sensitive to more recent changes in protein intake. The significant increase in the, initially relatively low, RBP in the S-C group by the end of the period of supplementation indicates that the provision of the nutritional supplements did improve the short half life protein status of this group of patients. After withdrawal of the supplements, the RBP dropped slightly, but by six months it was still significantly higher than the admission value, indicating that protein intake had been sustained. In contrast, the NS-CP group had demonstrated a (non-significant) decline in RBP by four weeks post-discharge, but that by 6 months their protein intake had returned to the pre-hospital value.

As already discussed in Chapter 3 (Feasibility study) at the time this current study was planned, there were no similar studies reported in the literature and the investigator was not aware of any similar work being undertaken in this group of patients, making it difficult to make appropriate comparisons between this work with that of others. However,
towards the final stages of this current study, reports of two very similar studies were published. The first was a Swedish study designed to evaluate the effect of dietary supplements on clinical outcome and nutritional status in a large group of 501 geriatric patients (Larsson et al., 1990). Two hundred and thirty-six of the 482 patients, who could be classified as either suffering protein energy malnutrition or not, were randomised into an experimental group and offered daily nutritional supplementation (400 kcal, 16 g protein) in addition to the standard hospital diet. In the description of the study, it is not made clear for how long the period of supplementation was maintained, but states that “patients were studied in a randomised fashion for up to 6 months of hospital care” and it may be assumed that supplementation was continued for the duration of hospital stay. Of the 236 eligible patients, 39 (16.5%) refused to take the supplements and they were discontinued from the study, leaving 197 to continue in the study. There is no further mention of the level of compliance, or any comment to suggest that this was monitored. All patients had their nutritional status assessed within the first week of admission, at 8 weeks and 26 weeks, by anthropology, serum protein analysis and a delayed hypersensitivity skin test. However, detailed examination of the data indicates that the number of data points which had been included in the final analysis had not been provided and in particular the number of patients followed to 26 weeks is unclear. Of the 246 patients initially randomised to the control group (receiving the hospital diet alone) eight had to be excluded from further study because they were so severely malnourished that nutritional supplementation had to be implemented. The remaining 238 underwent the same assessments as the experimental group. The patients were 190 males and 311 females, with mean ages 77.9 ± 9.3 (sd) years and 81.3 ± 7.7 years respectively, admitted for long term hospital care with a multitude of diagnoses. Some patients had up to five diagnoses, but the most common were, vascular disorders (207 cases), neurological impairment (167 cases),
heart disease (106 cases), endocrine disorders (88 cases) and fractures (79 cases). They all remained in hospital for at least three weeks. Although the patient population was not identical to that of the current study, the design was very similar and comparisons of outcomes shall be made later. Interestingly, even in this study of such a large number of patients, patients in the supplement group had a significantly lower body weight and MUAC (both p < 0.05) than the control group on admission. Despite the implications of this, as already discussed above, this important difference was not commented upon by the authors. Data were analysed according to the initial nutritional status of the patients.

In the initially malnourished patients, there was a pattern of decrease in the anthropometric parameters measured (MUAC, TSF) up to 26 weeks, in both the supplement and control (non-supplement) groups. The only exception was weight index (a percentage value derived from actual weight/reference weight), which was unchanged. Among those who were normally nourished initially, the supplement group showed significantly less loss in weight index after 8 weeks (p<0.05) and after 26 weeks (p<0.01); and significantly less decrease in arm muscle circumference after 26 weeks (p<0.05) compared with the control group. The decrease in TSF was greatest in the control group (although not significant). Serum albumin increased in all groups during the period of investigation but was described as being unaffected by nutritional intake. Similar changes were observed in prealbumin in both the malnourished and normally nourished groups, but there was a tendency towards a greater increase in prealbumin in the malnourished supplemented group, compared to the malnourished group who did not receive supplements. Prealbumin is more sensitive to change than albumin as it has a shorter half-life (approximately 2 days) similar to that of RBP.
The second relevant work to be published recently was a Swiss study (Delmi et al., 1990) of fifty-nine elderly patients (mean age 82 years) admitted to hospital with femoral neck fractures, 27 of whom were randomised to receive a daily oral nutritional supplement (254 kcal 20 g protein) for their duration of stay in both the acute and, if appropriate, the recovery hospital (mean 32 days). The remaining 32 patients acted as controls. The authors commented that "the supplement was well tolerated and completely ingested". Although the supplement was given at 2000 hrs in order not to interfere with scheduled meals, the reported compliance rate of 100% is exceptional amongst all studies of this type reported. Unfortunately no details regarding the method of ensuring or measuring compliance in all the patients were given by the authors and therefore no further comments can be made. In order to assess the effect of the supplements on normal food intake, a weighed dietary survey of all foods eaten at every meal was carried out for 16 patients (7 supplemented and 9 non-supplemented), over a period of 12 days during the post-operative course. All the patients underwent the anthropometric assessments of MAUC and TSF, and a blood sample was taken for the determination of serum albumin and RBP, within 24 hours of admission, on days 14, 21 and 28, on discharge from the convalescent hospital and at 6 months. Thus, the design of the study, duration of supplementation and patient population are similar to those of the current study. The admission values for several nutritional parameters, including RBP and TSF were below the normal range, or lower than reference values for elderly people living at home in Geneva. Serum albumin showed an initial drop in both the supplement and non-supplement groups, which then rose to significantly higher levels at days 14, 28 and 6 months in the supplement group. Results of the anthropometric changes are very similar to those observed in the current study, the initial drop being explained by a correction of the dehydration present on admission. Unfortunately the anthropometric measurements
were not repeated at the follow up assessments, but clinical outcome (frequency of complications, duration of stay in hospital, and mortality) was more favourable in the group receiving the supplements. These findings will be discussed in more detail later in this chapter.

Throughout the literature, low serum albumin values (< 30 g/l) on admission to hospital have been associated with greater rates of complications or mortality (Jensen et al., 1982; Foster et al., 1990; Patterson et al., 1992). The admission serum albumin values of the patients who died during the follow up period of the current study have already been discussed earlier in this chapter (4.5.2).

4.5.4 Changes in functional indices over the period of study.
In the current study, the changes in voluntary hand grip strength (vHGS) showed considerable fluctuations in all groups, which were not statistically different from the baseline assessment with the exception of the changes observed in the S-C sub group. A gradual increase in strength was observed in the S-C group up until 8 weeks post-discharge, at which time the value was significantly higher than on admission. These changes paralleled the increase in RBP, suggesting that although the protein intake was not sufficient to increase muscle bulk (as assessed by MUAMC), energy and protein intakes were sufficient to improve muscle function. The significant improvement in vHGS up to eight weeks was not sustained by six months post-discharge, but the values remained higher than on admission. Whilst the S-C group demonstrated an improvement in vHGS until the end of the period of supplementation (and beyond), the NS-CP group demonstrated a deterioration in vHGS over the same time period, but by 8 weeks post-discharge this had returned to the admission value which was sustained until 6 months. The changes observed in the S and NS groups were not significant. As already mentioned, if HGS reflects function
of other muscles, such as respiratory and heart, then these results imply that such muscles may be weakened following surgery and may render the patient less able to fight respiratory infections (see section 4.5.5 for discussion of rates of chest infections), or to maintain normal heart function. However, the subjective factors which influence HGS should be considered before extrapolating these results to the function of other muscles of the body. In order to remove these subjective influences, and therefore make a more objective measure of muscle function, it would be necessary to stimulate the muscle by an external electronic stimulus and measure involuntary contractility. There is such a method available but, since it involves submerging the arm in a water bath and applying electrodes to the abductor pollicis muscle of the thumb, it was considered impractical for use in this study.

It is over a hundred years ago since Quetelet (1842) reported a decrease in HGS as age increased. In a recent longitudinal study, HGS was measured in 487 people living in Edinburgh, aged 62-90 years, which was repeated 5 years later in 261 of the original sample (Milne and Maule, 1984). When the cross-sectional data were compared, there was a significant decrease of HGS as age increased. Of clinical predictive importance was the observation that mean HGS was significantly less in those who subsequently died, compared with the 5 year survivors. A significantly lower HGS in patients who subsequently died was also reported in a study of 82 consecutive admissions of female patients to a geriatric ward (Phillips, 1986). It was notable that those patients who subsequently died in the current study had extremely low vHGS on admission.

It was observed that many of the patients in the current study found the hand dynamometer very difficult to use and it was likely that the results would be falsely low. In retrospect, the use of a sphygmomanometer cuff,
as used by *Milne and Maule* (1984) would have provided more accurate and sensitive results.

In the current study, the changes in mental function test (MFT) scores were not significant in any of the groups. As all of the groups scored highly on the initial test, it would not have been possible for the score to improve significantly above this value. Patients with severe mental confusion on admission were excluded from the study and in only one patient did mental confusion persist beyond the immediate post-operative period. This was a lower proportion than was reported by *Matheny et al.* (1980), who noted that 25% of the 232 elderly hip fracture patients with no history of mental incompetence developed mental confusion during their hospital stay. In this large study, the mortality rate among those who developed mental confusion was 20.7%, compared with 1.1% in those who remained mentally clear throughout their hospital stay. Interestingly, this patient (in the current study) sustained several falls following discharge and an association between dementia and falls has been documented (*Brocklehurst et al.*, 1978), the cause of which appeared to be related to motor abnormalities rather than mental confusion.

The association between nutritional status and cognitive functioning in a healthy elderly population has been evaluated in 260 non-institutionalised men and women aged 60 years or above (Goodwin, *et al.* 1983) and results suggest that in this group of free living elderly subjects, nutritional status may influence cognitive status. More recently, biochemical indices of nutritional status have been related to cognitive performance and electroencephalographic (EEG) indices of neuropsychological function (*Tucker, et al.* 1990). The effects of severe protein energy malnutrition on personality and behaviour have been documented during wars and famine (*Brozek, 1990*). Progressive mental and physical lethargy, increased desire
for sleep, change in gait, increased proneness to accidents, decreased ability
to remember things and developing depression were the observations
reported. Many of these changes are associated with the process of normal
ageing, but to what extent, if any, they could be attributed to subclinical
malnutrition is unknown.

There are many tests available for the routine testing of mental status of
the elderly, varying in complexity and application. Full scale psychometric
tests, such as Wechsler (Wechsler, 1958) and Hunt-Minnesota (Hunt, 1943)
are relatively time consuming and require trained staff to administer them.
A disadvantage of using such tests in the elderly, is that they may lose
concentration, or become irritated, with consequent unreliable results. The
Information and Orientation section of the CAPE mental test score used in
the current study was probably not sensitive enough to identify any change
in mental status as a result of change in nutritional status and, in
retrospect, provided very little information. If a larger nutritional study
were to be conducted in elderly patients, it would be valuable to use a more
comprehensive method of testing mental ability, yet it must be simple and
relatively quick to perform. A simple questionnaire for testing memory,
vocabulary, calculation, orientation and speech, coupled with practical tests
using match sticks and toys, has been successfully used in elderly people
who were living independently (Silver 1972), but when used in geriatric in-
patients, many had difficulty with part or all of the test. If valid and
reliable results are to be obtained, care must be taken to chose a test which
not only evaluates the appropriate parameters, but it is also suitable for use
in the population being studied.

4.5.5 Clinical outcome.
Duration of stay in hospital is frequently used as an objective measurable
end point in studies which are designed to evaluate the impact of an
intervention on clinical outcome. In the current study, there was a significant difference in the length of stay in the acute hospital between the S-C and the NS-CP sub-groups ($p < 0.05$), but was not statistically different between the S and NS groups. The fact that the difference was not significant when the duration of stay was measured from the day of operation, instead of from the day of admission, implies that the patients in the S-C group had a longer pre-operative waiting time than the NS-CP group. The median difference in length of acute stay between the S-C and NS-CP sub groups was 4 days, but there was only 3 days difference in post-operative stay. Nevertheless, this three days represented a 23% longer stay for the NS-CP group and, if a larger group of patients were studied, this difference may have reached statistical significance.

Most studies which have investigated the relationship between nutritional status and length of stay in hospital have been undertaken in surgical patients where objective outcome criteria are easier to define. However, a relationship has also been found to exist for general medical patients (Anderson et al., 1985). In a study of 135 consecutive admissions, by use of a simple questionnaire and available laboratory results, the relationship between length of stay and various nutritional variables was explored. Of the variables studied, a recent weight loss of $> 10$ lbs had the highest specificity (75%), and serum albumin had the highest sensitivity (53%), when patients were categorised into those whose duration of stay was $< 8$ days, compared with those whose duration of stay was $\geq 8$ days. The financial implications of prolonged duration of stay have been highlighted in a study of 100 admissions to a general medical unit of a hospital in Pennsylvania where the hospitals are no longer reimbursed for the actual cost incurred for each patient, but instead are paid a fixed fee, calculated for diagnostic related groups (DRG's) (Robinson et al., 1987). In this study, patients were nutritionally assessed within 48 hours of admission and were
classified as malnourished, borderline or normal. Forty-five percent of the malnourished patients were hospitalised for longer than the time permitted under the DRG system, compared with 30% of the normal patients and 37% of the borderline group. Although the value of reimbursement was similar in all three groups ($4352-5124), the actual costs incurred were significantly greater in the malnourished ($16,691 ± 4389) and borderline ($14,118 ± 4962) groups compared to the normals ($7692 ± 687), (p<0.01). It is difficult to accept that with the supposed emphasis on high clinical and professional standards in advanced hospital care, that it takes the recognition of a financial implication before early diagnosis of malnutrition and provision of aggressive nutritional intervention are considered of importance in clinical practice.

The duration of hospital stay observed in the current study was less than that reported for 298 male and female patients with hip fractures treated with surgical intervention between 1972 and 1977 in West Virginia (Wallace, 1983). In this study, the mean hospital stay was 23 ±13 days for the survivors and 20 ±18 days for the deceased. The difference may be partly accounted for by an improvement in management over the past 15 years, as well as the inclusion of elective surgery admissions in the current study. Although the figures for the current study have not been presented separately for the survivors and non-survivors, as only one patient died during the stay in the acute hospital (15 days after admission), this is unlikely to influence the results greatly.

The effect of protein depletion on duration of stay in hospital has been highlighted in the study of hip fracture patients by Patterson et al (1992), who reported the mean duration of stay in hospital to be 19 days. The mean duration of stay for the patients categorised as protein depleted was 21
days, compared with a mean stay of 15 days in the non protein depleted patients.

Of course, there are many factors which determine length of stay in the acute hospital, such as the type of prosthesis used in surgery, the individual surgeon's opinion on post operative care, the availability of a bed in a convalescent hospital or the social circumstances into which the patient is discharged. It is therefore important to study the differences in length of stay in the convalescent hospital, where these other factors do not have such strong influence. In the current study, the differences in median duration of stay in the convalescence hospital was 9 days between the S and NS groups (p < 0.05) and 18 days between the S-C and NS-CP sub-groups (p < 0.01). When the total stay in both hospitals was added together, the difference was 11 days between the S and NS groups (p < 0.01) and 27 days between the S-C and NS-CP sub-groups (p < 0.01). Similar differences in total length of stay have been reported by other workers performing a similar study in 59 elderly patients (mean age 82 years) with femoral neck fractures, the details of which have already been described (Delmi et al., 1990). In the 27 patients who received a daily oral nutritional supplement containing 254 kcal and 20 g protein, the median duration of stay in the orthopaedic (acute) and recovery (convalescence) hospitals combined was significantly shorter in the supplemented patients [median 24 days (range 13-157)] than the non-supplemented patients [median 40 days (range 10-259)] (p<0.02). In this analysis, patients who died before discharge were not included in the calculations. The six patients who died during the course of the current study were included in the analysis.

In the present economic climate, with cutbacks in NHS expenditure and emphasis being placed on productivity, the results from the current study have important implications. If one of the aims of improving the efficiency
of the hospital care system in the UK is seen to be fulfilled by reducing the length of stay in hospital, then it would be valuable to understand what specific stages of hospital care account for the total stay. This approach was used in a prospective study of the acute hospital care received by 216 patients with femoral fractures admitted to the trauma and orthopaedic service of a Californian health district over a twenty week period (Robbins and Donaldson, 1984). Of the 216 patients, 199 underwent surgical treatment. The remainder were treated conservatively (12) or died before surgery (5). Of the 5167 patient-days of acute hospital care, 492 (10%) were spent awaiting surgery; 141 (3%) being made fit for surgery; 2690 (51%) recovering from surgery without complication; 59 (1%) were being treated for surgical complications; 56 (1%) were being treated for medical complications; 1437 (28%) were awaiting discharge after surgical and medical care were complete and 292 (6%) were spent by patients receiving conservative treatment. Although these figures would undoubtedly vary considerably from centre to centre, they suggest that innovations to hasten recovery, for example nutritional support, are not likely to have a major impact on overall length of stay in the acute hospital. Such factors may, however, be important in determining long term function or mortality. The median total length of stay in the acute hospital, for the 216 patients was 20 days. A less comprehensive, but similar study of 226 Stockport residents aged 60 years or over, admitted to hospital with a proximal fracture (202 of whom were treated surgically) revealed that the 266 cases occupied 12,027 days in hospital in the first six months after fracture (Greatorex, 1988). The mean duration of stay was 53.2 days, of which 31.6 were in an acute orthopaedic bed, 16.0 in a rehabilitation bed and 5.6 in a continuing care bed. The median duration of hospital stay was 30 days and 20 cases (10%) were still in hospital at six months.
The most important consideration when a patient is discharged from the convalescence hospital, is that the patient is in an appropriate state of health to be able to cope in their new environment. If the early discharge of patients results in problems later, which imposes not only additional requirement on already stretched resources, but also is likely to cause suffering and a reduction in quality of life for the patient, then these economies are false. It is therefore important to consider the degree of independence, complication and readmission rates of the patients in the current study. The Visick score, used in the current study, is a semi-objective index of independence and reflects the ability to perform activities associated with daily living. As the fracture patients are confined to bed on admission and the acute hospital is an artificial environment, it was regarded as inappropriate to use the Visick score until after discharge from the acute hospital. The first assessment was made between one and two weeks after discharge from the acute hospital, when the median scores of the S and NS groups (and of the S-C and NS-CP sub-groups) were identical. Both the S-C and the NS-CP sub-groups showed an improvement in independence over time, as may be expected as recovery progressed but the improvements were significantly more rapid in the S-C sub-group up until the assessment at 8 weeks post-discharge. By six months, although the score still reflected a greater degree of independence in the S-C sub-group, the overall change from the initial value was no longer different from the NS-CP sub-group. In other words, although the end points were similar, the NS-CP sub-group took longer to achieve them than the S-C sub-group. The pattern of comparison between the S and NS groups was similar, although the levels of significance were less, probably reflecting the dilution effect of including patients who did not comply to the supplement regimen.
The circumstances of living and interpretations of the Visick scores of patients in the current study, can be compared with the ambulatory status and independence of 40 hip fracture patients reported by Foster et al (1990). At three months after their hip fracture, 37.5% had returned to their pre-fracture ambulatory status; 42.5% sustained a decrement in their ambulatory status or independence; 12.5% had died and 7.5% were lost to follow-up. In the current study, by 8 weeks post-discharge, 16 (76%) patients in the S group and 15 (71%) in the NS group had returned to their pre-fracture place of living. Although these proportions are similar, differences are observed between the patients who consumed the supplement and their admission pairs. Ninety-two percent of the S-C subgroup compared with only 46% of the NS-CP sub-group had returned to their original circumstances by 8 weeks post discharge. The median Visick score of the S-C subgroup at 8 weeks post-discharge showed an improvement in independence since discharge, whereas there was no change in the median Visick score of the NS-CP sub-group since discharge. These results imply that the sub-group consuming the supplements regain pre-fracture mobility and independence quicker than would be expected from the natural course of recovery, as demonstrated by the data from the matched pairs of the sub-group not being offered the supplements (NS-CP).

A more appropriate study for comparison may be that of Cummings, et al (1988), in which 76% patients (86% of whom were over the age of 60 years and 68% of whom were female) reported poorer functional status at 6 months after the fracture as compared to their pre-fracture state. In the current study, most of the patients had returned to their original way of living by the end of the 6 month follow-up period, but the Visick scores indicated that many of the patients in the NS-CP sub-group were not functioning independently. It was apparent from conversations with the patients that they considered themselves to be in a poorer functional status.
than they were pre-fracture. A longer period of follow up, in 105 patients one year or more after femoral fracture, revealed that 25% of this group had become more dependent since their accident (Glyn Thomas and Stevens, 1974). The principal factors contributing to this outcome included established dependence, greater age at time of injury and poor clinical result. In the current study, these factors were evenly distributed between the S-C and NS-CP sub-groups, yet differences in outcome were observed, suggesting that the provision of nutritional supplements may have an effect on functional outcome and therefore, independence.

Even minor fractures can have an impact on social and functional independence of elderly people (Nankhonya et al., 1991). In a prospective study, 105 patients (93 of whom were female) attending a fracture clinic in the Wirral (mean age 77 years, range 70-89) were interviewed. Sixty-five (62%) of the patients stated that they required help in the home, especially during the first two to four weeks after sustaining the fracture, most of which came from relatives or neighbours. Fifteen were regarded as being severely disabled by their injury and a further 59 had a moderate functional disability on the modified Barthel activities of daily living index. The use of the Barthel Index in this study can be criticised because it was developed for use in patients with long term musculo-skeletal and neuro-muscular disorders (Mahoney and Barthel, 1965) whereas management of minor fractures entails near total immobilisation and non-weight bearing of the affected limb which directly influences the score of the Barthel Index. However, the study highlights the importance of the fact that the first few weeks following fracture are the most difficult. It reinforces the need for as much support as possible to be given to the patient at this time. This would include nutritional support, as meal preparation may be too demanding to perform adequately.
Throughout the period of study, one patient in the S group and two patients in the NS group reported having one or more subsequent falls. The fact that this resulted in a broken ankle for one patient and a dislocated shoulder for another, highlights the seriousness of the effects of repeated falls.

Further information on clinical outcome can be obtained by studying the number of patients experiencing infections or pressure sores during the study period. The NS and NS-CP groups showed significantly greater incidence of both chest infections and pressure sores when compared with the incidence in the S and S-C groups respectively.

The effect of malnutrition on infection and mortality rates has been studied in underprivileged countries where there is a high prevalence of malnutrition. The effect of this severe malnutrition on the immunological response has been particularly studied in children of these countries (Neumann et al., 1975; Chandra, 1983), but the effect of more subtle malnutrition in comparably "well nourished" hospital patients in relatively affluent countries has received less attention. Trauma and major surgery have been shown to induce a state of malnutrition and loss of immunocompetence in a heterogenous group of patients undergoing orthopaedic surgery (Jensen et al., 1982). In a more recently published study of 482 newly admitted elderly patients, nutritional state was assessed by anthropometry, serum protein analysis and delayed hypersensitivity skin testing (DH), on admission and after 8 and 26 weeks (Ek, et al. 1990). Immunological competence was measured by an intracutaneous injection of three recall antigens and the area of induration was measured after 48 hours. Of the 488 patients studied, anergy was found in 63.2% and was significantly higher in those over 79 years of age (p < 0.001). In the anergic group (n=307), 45.4% were malnourished and 28% had pressure sores on
admission or developed sores during the observational period. In the group of patients randomly allocated to receive nutritional support, a significant increase in the number of patients with reactivity was observed after 8 weeks \((p < 0.02)\) and 26 weeks \((p < 0.01)\). In comparison, the control group did not alter in reactivity during the study. Mortality was also higher in the patients with anergy. The mortality rates observed in this study will be discussed later in this chapter.

After diagnosis of a wound infection, patients in the current study were given a course of antibiotic treatment, but one question which arises is whether the infection could have been prevented by the prophylactic pre-operative administration of antibiotics. The role of prophylactic antibiotic treatment to prevent post-operative wound infection is an appealing routine to the surgeon, particularly the orthopaedic surgeon whose work often involves extensive wound injury and the implantation of metal or polymeric structures into the body. However, the clinical value of prophylactic use of antibiotics in patients with a fractured femur remains a topic for debate (Burnett et al., 1980). Infection is reported as being seen in approximately 2% of patients undergoing a total hip replacement (Smith, 1989) and many surgeons do advocate prophylactic antibiotic drugs.

Pulmonary complications remain the most important cause of post-operative morbidity and mortality and, despite the advances in surgical care over the past 30 years, the incidence of these complications has altered appreciably (Windsor and Hill, 1988). A study of 80 male and female patients awaiting major gastrointestinal surgery (age range 15-91 years) observed that pneumonia developed in a significantly higher proportion of those patients who were categorised as protein depleted prior to surgery, compared with those who were categorised as non-protein depleted. (Body composition being determined by neutron activation analysis and the tritiated water
dilution technique.) There was a significant difference between the two groups with regard to respiratory muscle strength (p < 0.025), vital capacity (p < 0.05), and peak expiratory flow rate (p < 0.005). It has been suggested that protein depleted patients are more susceptible to pulmonary complications because of an ineffective cough secondary to expiratory muscle weakness (Arora and Rochester, 1982). The results of the current study suggest that nutritional support may prevent the onset of chest infections and therefore reduce the risk of pneumonia developing, by the observation that only one patient in the S group experienced a minor chest infection, compared with six in the NS group. Two of the patients in the NS group later developed pneumonia.

In the current study, although mortality was not significantly different between the S and NS groups, it was significantly greater in the NS-CP sub-group than the S-C sub-group by four weeks post-discharge, the end of the period of supplementation. By the end of the period of study, the statistical significance of the difference in mortality rate between the S-C and NS-CP sub-groups had increased. It is well documented that the highest mortality rate is within the first few months following surgery for a fractured femur. (Dahl, 1980; Gordon, 1971; Miller, 1978; Steen Jensen & Tondevold, 1979). Of the five people who died during the period of study, two were aged ninety years or over and therefore death was perhaps not unexpected. Interestingly, two of these patients were originally allocated to the S group but had failed to comply to the regimen. It would seem difficult to comprehend that the provision of nutritional supplements may reduce mortality during the post-operative few months, but similar differences in mortality in elderly patients admitted to hospital for repair of a fractured femur, have been observed between those receiving nutritional supplements and a similar group not receiving nutritional supplements (Larsson et al. 1990; Delmi et al. 1990). In the study of 501
geriatric general medical patients (Larsson et al., 1990), a higher rate of mortality was observed among the initially malnourished patients than the well nourished patients ($p < 0.01$). In the group of 321 patients who were initially well nourished, 18.6% died in the control group, compared with 8.6% in the group receiving nutritional supplement, similar mortality rates to those reported in the current study. In another study (Delmi et al., 1990), of the 27 elderly patients with femoral fractures who were randomised to receive nutritional supplements, 6 (24%) had died between discharge from the recovery (convalescence) hospital to the 6 month assessment (two unaccounted for). This compared with 10 (37%) in the group of 27 who had not received nutritional support. What is perhaps of more clinical relevance is that there were no deaths in the supplement group after discharge from the recovery hospital, compared with 6 in the non-supplement group. This again is similar to the findings of the current study.

Surgical correction of fractured neck of the femur in the elderly is a procedure generally recognised as being associated with a high rate of post-operative morbidity and mortality. The possible influence of the type of anaesthesia was a factor which was investigated during the 1970’s and 1980’s. It was McLaren, Stockwell and Reid (1978) who first suggested that subarachnoid block (spinal analgesia) was associated with a reduced early mortality compared with general anaesthetic. However, a much larger multicentre study of 538 patients found no significant difference in 28 day mortality between the two techniques (Davis et al., 1987). Interestingly, in the latter study, a delay in surgery of more than 24 hours from the time of admission was associated with an increased 28-day mortality. The four patients in the current study who died, all received surgery on either the same day of admission, or the next day. Unfortunately the time of admission and operation were not documented by
the investigator and therefore no further comments can be made with respect to the delay in awaiting surgery.

The importance of the effect that technical aspects of the surgery may have on the outcome has been investigated by Pettigrew et al (1987). In this prospective study of 113 surgical patients having elective resection of the alimentary tract, a pre-operative clinical and nutritional assessment was made of each patient in an attempt to determine the risk of major complications. In addition, the surgeon performing the operation made a risk assessment on a linear analogue scale before and immediately after the operation. The surgeons pre-operative assessment was able to predict some of the 28 (25%) of patients who developed complications, but the predictive power of their post-operative assessment was much greater. The reason given for the change in risk assessment in 36 (82%) of the 44 patients whose ranking changed, was the technical ease or difficulty of the procedure. It was concluded that immediate post-operative assessment was superior to any pre-operative method of selecting high risk patients, although patients with a low serum albumin (< 29 g/l) on admission developed significantly more complications. It has also been reported that a technical problem was the cause of post-operative instability in the fracture of 23 (11%) of 202 patients who were treated surgically for repair of fractured femur (Greatorex, 1988). Sixteen of these patients required a second surgical operation and another patient required two further operations within six months. Six of these further operations were total hip replacements. Three of the 40 hip fracture patients in the study of Foster, et al (1990) required a second orthopaedic procedure within the follow up period of 11 months. In the current study, only one patient (2%) was readmitted for a second surgical procedure, which was related to the original prosthesis, but there were two further emergency admissions as a result of falls, and one elective admission for a total knee replacement.
The lower readmission rates reported in the current study are likely to be due to the fact that the patient group was comprised of one third total hip replacements, in whom the incidence of a repeat operation is much less (Smith, 1989).

4.5.6 Dietary intakes.

4.5.6.1 Nutritional Intakes from supplements

The median daily nutrient intake from the consumption of the supplements in the current study was 230 kcal and 19.4 g protein, consumed in approximately 205 mls whilst in the acute hospital. This rose to a median of 260 kcal and 19.4 g protein, consumed in approximately 200 mls/g during the post-discharge period of supplementation. The greater consumption of Fortimel, which has a higher protein : energy ratio, can account for the differences in intakes during this post-discharge period. The level of supplementation achieved did not reach the target intake of 2-3 supplements (500 kcal) per patient either during hospitalisation or following discharge. Despite offering a range of supplements, the daily calorific value and volume of the supplements consumed in the current study was only half that attained during the feasibility study (Chapter 3), the mean intake being 400 kcal in 400 mls. Although daily energy intake from the supplements was lower, the protein intake was similar (mean daily intake feasibility study being 14.1 g) suggesting the possibility that the supplement consumed may be self-regulated by the content of

This could also explain why the level of supplementation attained by other workers varies in energy content, but is similar in protein content. The dietary supplement offered in the randomised study of geriatric patients (Larsson et al., 1990) was 400 kcal and 16 g protein, a similar nutritional value to that of the supplement used in the feasibility study. In the study
of Delmi et al (1990), the elderly fractured neck of femur patients were reported to have "completely ingested" a nutritional supplement containing 254 kcal and 20 g protein in 250 mls each day, and earlier workers had provided a supplement containing 18.5 g protein and 320 kcal to a similar group of elderly women with femoral fractures (Stableforth, 1986). However, differences in compliance rates should also be considered.

4.5.6.2 Nutritional Intakes from normal foods (24 hour recalls)
There were no significant differences in the protein or energy intakes estimated from normal foods, for the S and NS groups, on any of the 24 hour recall assessment days throughout the study. There was a trend for protein intakes to be higher in the supplement group. This suggests that the provision of the nutritional supplements did not adversely affect normal food intake. Throughout the period of study, there were no significant differences in protein or energy intakes within the groups, although a trend towards increasing protein intake with time was observed in the NS group suggesting that with no nutritional intervention energy and protein intakes would improve with time.

When the energy and protein intakes from normal foods for the S-C sub group were compared with the intakes of their matched admission pairs from the NS group (NS-CP), both protein and energy intakes were higher in the S-C sub group at each of the assessment periods. At the hospital assessment the median intakes of the NS-CP sub-group were 868 kcal energy and 29.6 g protein and at the assessment made four weeks after discharge the median intakes were 1154 kcal energy and 49.8 g protein. The differences between the intakes of the S-C and NS-CP sub groups were statistically significant for both protein (p < 0.01) and energy (p < 0.05) at the hospital assessment. Although there were no statistically significant differences within either sub group, a clear trend of increasing protein and
energy intake was observed in the NS-CP sub group. The intakes of the S-C sub group are relatively consistent over the period of study and, in comparison, the intakes of the NS-CP sub group were lower whilst in hospital and showed an increase in protein and energy intakes on each of the two subsequent assessment days. These results suggest that the consumption of the supplements may act as an appetite stimulant over a period when normal food intake would otherwise be impaired. It could, however, be argued that the S-C group may be a "self selected" group who naturally have a higher than average food intake and, if the supplements were not provided, their nutritional intake from normal foods would be higher. However, as this group had a poorer nutritional status on admission, this is unlikely to be the reason.

Thus, the observations of initially low, but then increasing food intake of the NS group is likely to be the normal course of progress if no nutritional intervention is offered. Of notable importance was that this progressive intake of normal food was not observed in the group of patients who were offered the supplements, but who did not consume them (the S-NC sub group). In this group of patients the intakes of both protein and energy were significantly reduced at the six month assessment, when compared with all other sub groups (p < 0.01) and when compared with their nutritional intakes whilst in the acute hospital (0.02). This suggests that the patients who refused the supplement may be those who are the most vulnerable to nutritional depletion. Therefore additional attention, aimed at improving compliance, is warranted, particularly in this group of patients.
4.5.6.3 Total nutritional Intakes from normal foods and the supplement combined

With the intake of normal foods being similar or higher in the S and S-C groups, compared with the NS and NS-CP groups respectively, the consumption of nutritional supplements further improved the energy and protein intakes in the group of patients who consumed them (S-C). The consumption of supplements in the S-C sub group of the current study resulted in an increase of 16% in energy intake (from 1366 kcal to 1549 kcal (median values)) and 23% in protein intake (from 63.3 g to 77.8 g (median values)), above that consumed from normal foods whilst in hospital. At four weeks post-discharge, the increases were very similar, being 22% in energy intake (from 1273 kcal to 1553 kcal (median values)) and 26% in protein intake (from 62.5 g to 78.8 g (median values)). At the 6 month post-discharge assessment when the supplements were no longer being offered, the median daily intakes of energy and protein of the S-C sub-group were 1468 kcal and 61.3 g protein, respectively. Thus the combined nutritional intake from normal foods and the supplement for the S-C sub-group were similar at both the hospital and four week post-discharge assessment. By six months post discharge, the energy intake from normal foods alone had reached a similar level to that of the normal food plus supplement during the early convalescence period, and protein intake was not significantly less than the combined intakes at the previous assessments. These results suggest that the consumption of the supplements enabled the patients to ingest more calories and protein, which would not otherwise be consumed from normal foods, to a level which would not otherwise be achieved until much later into the discharge period.

An observation which is likely to be of clinical importance is that there were 15 assessments in the NS group at which the total energy intake was less than 1000 kcal/day, 5 of which were below 500 kcal/day, compared with only
three assessments in the S group when the total energy intake was below 1000 kcal/day, only one of which was less than 500 kcal/day. The observations are similar when considering protein intake. In the NS group, there were six assessments made where the protein intake was less than 20 g/day, compared with only one in the S group. Although these intake levels have been chosen arbitrarily, they do highlight the low nutritional intakes from normal foods in this group of patients. Of the six patients who died during the period of assessment, five of them consumed less than 1000 kcal/day or 20 g protein/day on at least one of the assessment days. This observation does not necessarily imply a causal relationship, but there may be a strong case for implementing a more aggressive form of nutritional support in patients whose nutritional intakes are observed to be deteriorating rapidly. The nutritional intakes are reflected in the anthropometrical, biochemical and functional assessments in these groups, as discussed previously.

4.5.6.4 Comparison of nutrient intakes with Department of Health (1991) recommendations.

Considering the nutritional value of the normal foods alone, 16% of the S and 50% of the NS group consumed less than the current recommended daily intake of protein and none of the patients was able to meet the estimated average daily requirement for energy (Department of Health, 1991) on the day of assessment during the acute hospital stay. At the four week and six month post discharge assessments, the percentages of patients failing to reach the target for protein and energy intakes were decreasing in the NS group, indicating that more patients were meeting their basal nutritional requirements from normal foods alone. In the S group, the percentages of patients not meeting the recommended intake for protein had increased by the four week assessment and again by the six month assessment, whereas the percentage of patients not meeting the
requirement for energy had decreased by four weeks, but then returned to 100% by six months. These results could suggest that the provision of nutritional supplements whilst in hospital served to increase intake of normal foods with a high protein content, but by the four week assessment this apparent stimulation was beginning to diminish and by six months the natural appetite had returned. To evaluate this more closely, it is necessary to study the intakes of the S-C sub group compared with the NS-CP sub group.

The provision of supplements whilst in hospital increased the nutritional intake of the patients in the S-C sub group to the extent that all patients met the current recommendations for protein, yet 82% of the S-C sub group failed to meet the recommended intake for energy. Four weeks after discharge from the acute hospital, 15% of the patients in the S-C sub-group had intakes below the current recommendations for protein and 77% had intakes below the recommendations for energy. At six months post-discharge, when the supplements were no longer provided, none of the S-C patients attained the recommended energy intake whereas, the majority of the patients in this group (92%) did meet their recommended protein intake. In comparison, in the NS-CP sub group 73% of patients failed to meet their current recommended intakes for protein whilst in hospital, 45% at four weeks and 14% at six months. The percentages failing to meet the requirements for energy were 100%, 91% and 86% at each of the assessment times respectively. These results indicate that the supplements were most effective at increasing protein intake.

Considering that the current recommendations (Department of Health, 1991) are for the healthy free-living elderly, and it has been suggested that a factorial increase of 30% is required following surgery (Stableforth, 1986) such low intakes are cause for concern. Indeed Reilly et al (1988)
suggested that a daily intake of 30 kcal and 1.5 g protein per kg body weight would be sufficient to offset the increased requirements of trauma in elderly patients admitted to hospital for surgical repair of a fractured femur. As the median body weight of the S group was 42.6 kg, this would correspond to an intake of 1278 kcal and 63.9 g protein per day. The median intakes of the S-C group exceeded these calculated requirements by 271 kcal and 14.5 g protein (median intakes being 1549 kcal and 77.8 g protein) yet the group still showed a decline in parameters of protein status. This suggests that these calculated values may be an underestimate of requirement in the early post-operative period.

4.5.6.6 Comparison with other workers
The level of supplementation achieved in the current study was similar to that achieved in the same patient population by Delmi et al (1990), in which a 200 ml supplement containing 254 kcal and 20g protein was given each day, and was reported to be completely ingested. As already discussed, the results obtained with respect to length of stay and clinical outcome were also similar. In this study, the voluntary intake of food during hospitalisation resulted in a mean intake of 1100 kcal (± 300 sd), which was similar to the mean energy intake at the hospital assessment of both the NS group (mean 1107 kcal ± 520) and the S group (1249 ± 291 kcal) in the current study. The mean protein intake, however, of 34 g (± 11 sd) was less than the mean intake of patients in the NS (46.4 ± 28.8 g) and S (56.9 ± 14.7 g) groups in the current study at the hospital assessment. However, the individual variation was large and, from the description of methodology given in the Delmi (1990) study, it seems that only foods eaten at meal times were recorded, whereas the nutritional intake in the current study includes food and snacks taken between meals, which may partially account for the lower values reported in the Delmi (1990) study.
The intakes reported in the current study are also similar to those of elderly women admitted to a ward of acute orthopaedic surgery where each patient’s meals and snacks were weighed for an average of 16 days (Hessov, 1977) during which the mean daily energy intake was reported to be 1163 ± 341 kcal. The mean intake of protein was 0.7 ± 0.3 g/kg/day, equating to 29.8 g/day if multiplied by the median body weight of 42.6 kg observed in the S group of the current study. In this study, the low protein intake was attributed to a low overall intake of food and a high consumption of refreshing drinks and titbits, both containing little nourishment. Low protein intakes were also reported by Stableforth et al (1986) being 887 ± 350 kcal and 27.0 ± 11 g protein from the ward diet alone, which rose to 1075 ± 190 kcal and 40.0 ± 11 g protein per day with the addition of a nutritional supplement. It could be speculated that the supplements provided in the current study could partly have replaced the desire for less nutritional drinks and snacks and led to a higher protein intake, particularly during hospitalisation. The failure of hip fracture patients to ingest adequate protein or calories has also been reported by Patterson et al (1992). This study reported that none of the sixty-three patients studied consumed sufficient calories to meet basal requirements during the first week after surgery, despite the provision of a high calorie, high protein liquid in the post operative period.

Higher intakes have been reported in long stay hospital elderly patients, ranging from 2226 ± 462 kcal to 2394 ± 630 kcal and 42.8 g protein to 50.5 g protein per day (Thomas et al., 1988; MacLellan et al. 1975; Vir and Love 1979). However, these studies used more rigorous methods of assessment (16 day weighed dietary record, 7 day record or 3 day weighed record respectively) and male patients were included in the evaluation. If the dietary intakes of the patients in the current study at the six month assessment are compared with similar groups of elderly people living in the
community, then they were lower. Several community studies have used more detailed methods of assessment (7 day diaries, 3 day weighed food intakes or 5 day duplicate analysis) to evaluate nutritional intakes and have reported intakes as high as 2016 ± 378 kcal/day and 39.1 g protein/day in housebound elderly (Bunker et al., 1987) to 3000 ± 714 kcal/day (DHSS, 1979) and 60 ± 13 g protein per day (Macleod et al., 1979).

Again the inclusion of male patients is likely to increase the mean intake, but nevertheless, these values are higher than those consumed by patients in the current study, implying that they are less able to replenish nutritional stores in the period during which another surgical procedure is likely in a proportion of patients.

A more recent study comparing the nutritional intakes of elderly day hospital and day centre attenders reported that the average daily energy intakes of the women attending the day hospital were 1747 ± 456 kcal, compared with 1811 ± 383 kcal/day in the day centre attenders (Mowat et al., 1992). Corresponding mean daily protein intakes were 66 ± 12 g/day in the day hospital patients compared with 67 ± 12 g/day in the day centre attenders. The method used by these workers to obtain these results was the diet history method of interview and a 24-hour dietary recall. The method of 24 hour recall alone, which was used in the current study, can be criticised as it represents only one day of a greater time period and the accuracy of portion sizes is questionable. During the current study, the resources were not available to conduct a more detailed assessment. It was recognised that this method of assessment does not confer a high degree of accuracy and may not be representative of usual intake. Therefore a more detailed assessment of the effect of supplements on voluntary food intake was performed later with a similar group of patients. The results of this will be presented and discussed (Chapter 5).
The provision of dietary supplements has been demonstrated to increase the intake of energy by 23% and the intake of protein by 62% (Delmi, 1990). These increments equate to a mean combined nutritional intake of approximately 1350 kcal and 55 g protein (probably excluding snack items), similar to that achieved by the S-C sub-group of the current study.

A higher level of supplementation was achieved in the large study of long stay elderly medical patients (Larsson et al., 1990), in which a supplement containing 400 kcal and 16 g protein was offered to the patients. A major criticism of this study is that no reference was made to the level of compliance, the duration of supplementation, or the effect on normal food intake. These workers did, however, touch on an important issue rarely mentioned by researchers in this area, that is the effect that the provision of supplements has on the well-being of the patient. These workers reported that the well-being of the patients had been evaluated in another study using the Norton Scale (not referenced). This scale covered the patients' general physical condition, mental state, mobility and activity. Preliminary results reported improvements in both the supplement and control groups, but the improvement was more marked and occurred earlier in the supplemented group (Unosson unpublished data). The use of measures of well being and quality of life will be discussed briefly in Chapter 6 (General discussion).

The question as to whether the provision of additional energy and protein, in the form of supplements, leads to a reduction in these nutrients being consumed from normal foods, is one of fundamental importance. The results of the current study imply that the consumption of supplements certainly does not lead to a reduction in energy and protein intake from normal foods, and may even suggest that the supplements may simultaneously increase the nutrient intake from normal foods. The
observation that the nutritional intakes of the group consuming the supplements were similar at each assessment, could suggest that the patients may self-regulate their nutritional intake to a certain level, and any attempt to increase the level of supplementation may cause a reduction in the nutritional intake from normal foods. However, evidence from the overnight nasogastric feeding study of Bastow et al (1983a) appeared to alleviate this concern. In this study 1000 kcal and 28 g protein per night, in addition to the normal ward diet, resulted in a reduction of voluntary food intake of less than 300 kcal. On balance this is not a serious cause for concern when the level of supplementation is this high and this method of nutritional support should be considered for patients with very low energy and protein intakes where sip feed supplements of sufficient nutritional content are not tolerated. A more detailed evaluation of the effect of consuming nutritional supplements on normal food intake will be performed (Chapter 5).

Although the reasons for non acceptance which were given by the patients all related to the sweetness and consistency of the supplement, the investigator's personal perception was that patient attitude to nutrition and life in general were important. As a subjective observation, those patients who considered the supplements to be of benefit consumed them and those who considered them to be unimportant, did not. If these patients could be enlightened as to the role of nutrition in the recovery process, maybe compliance could be improved. The effect of nutritional education on patient compliance to the regimen will be investigated further (Chapter 5).
4.6 SUMMARY AND CONCLUSION

The Nutrition Risk Questionnaire identified a group of nutritionally vulnerable individuals categorised 57.5% as high risk (HR), suggesting that a significant proportion of the elderly female patients admitted for orthopaedic surgery are at risk of being nutritionally compromised.

At the initial assessment, there were no statistically significant differences between the S and NS groups with respect to TSF, serum albumin, serum RBP, vHGS, mental function score, or the constituents of the routine hospital blood tests. However, the S group had significantly lower admission values for body weight, and anthropometric indices of protein status (MUAC and MUAMC).

During the period of supplementation (post-surgery until four weeks after discharge from the acute hospital), the NS group demonstrated significant decreases in body weight, MUAC (until discharge) and MUAMC. In contrast, the S group demonstrated a non-significant increase in body weight, a less significant decrease in MAUC and a less significant decline in MUAMC (until discharge only). Restoration of body fat and protein stores, as indicated by the anthropometric indices, were slower to return to the pre-admission values in the NS group, than the S group. Serum albumin and RBP assessments suggested that the provision of supplements could reduce the loss of body tissue which would otherwise occur as a result of major trauma and surgery. It could, however, be argued that the differences in baseline values could account for the differences in the response of the patient.

No significant changes were observed in the functional assessments of either the S or NS groups, the methods used were considered to be
influenced by non-nutritional factors or were insufficiently sensitive to change.

The duration of the time required in convalescence was significantly greater in the NS group. The incidence of common complications (urinary tract infections, chest infections and pressure sores) were significantly greater in the NS group, compared with the S group, suggesting that the provision of supplements may improve immunocompetence and ability to resist infection. The mortality rate observed in the NS group was similar to that reported in the literature for this patient population, but was only half of this "expected" rate in the S group. This difference did not reach statistical significance.

It should be remembered that only 60% of the patients offered the supplement consumed it. By sub-dividing the S group into compliant (S-C) and non-compliant (S-NC) sub groups, and comparing the outcomes of the S-C sub group with their admission pairs from the NS group (NS-CP) therefore applying "per protocol" analysis to the data, the impact of nutritional supplementation was evaluated. Observations were similar to those observed in the S and NS groups respectively, which suggest that the effects of the supplements were strong enough to be recognised even when the "intention to treat" analysis was used and the results from the non-compliant patients were included.

The duration of stay in the acute hospital was significantly shorter in S-C than the NS-CP group, although the significance was lost if pre-operative waiting time was excluded. The difference in time spent in a further period of convalescence was of greater statistical significance when comparisons were made between the S-C and NS-CP sub groups, than when comparisons were made between the S and NS groups. A significantly greater number
of patients in the S-C group had returned to their pre-hospital environment by 8 weeks post discharge than in the NS-CP group and this was reflected in the independence of mobility scores. Infection rates were significantly lower in the S-C group and as no patient from the S-C group died during the study period, the differences in mortality reached statistical significance.

The nutrient intake data suggested that the supplements may act as an appetite stimulant, however the method of assessment (24 hour dietary recall) can be criticised. This will be addressed further in Chapter 5.

The nutrient intake data also suggested that the patients who chose not to comply to the supplements showed a decline in food intake over the course of the study. It could be deduced that the patients who refuse the supplements may be those who are most at risk from the consequences of nutritional depletion and therefore the use of more invasive nutritional support may be warranted in this group of patients. Before this is implemented, it is important to investigate further whether any other measures can be taken to encourage voluntary compliance. The role of patient nutrition education will be investigated in Chapter 5.
Chapter 5

The Effect of a Nutrition Education Programme on Patient Compliance to Sip Feed Supplements and Further Investigations Regarding the Effect of Supplement Consumption on Nutritional Intake from Normal Foods
5.1 INTRODUCTION

Compliance to the nutritional supplements has been reported as being very poor in both the feasibility study (Chapter 3) and the long term study (Chapter 4). In the feasibility study (Chapter 3), seven of the eighteen patients who were offered the nutritional supplements (39%) refused them either at the outset or after consuming only a minimal amount. In an attempt to improve the rate of compliance, a choice of supplements was offered to patients who participated in the long term study but, despite this, the compliance rate was unaffected (Chapter 4) with eight of the twenty-one patients (38%) again refusing the supplement or consuming only minimal amounts. The main reasons given for not wishing to continue with the regimen was that the supplement was considered to be too rich, sweet or sickly. Interestingly, in the long term study, the volume and hence the nutritional value of the supplements was less than in the feasibility study. The mean volume of supplement consumed throughout the hospital stay for the patients in the feasibility study was 400 mls (400 kcal, 14.8 g protein), compared with a mean of 217 mls/g (223 kcal, 17.8 g protein) for the patients in the long term study during hospitalisation and 246 mls/g (262 kcal, 22.7 g protein) in the post discharge period. Clearly, offering a choice of supplements does not improve compliance, suggesting that flavour is not the main determinant of whether the supplements are taken by the patient. If the provision of sip feed supplements is to be an effective method of nutritional support in nutritionally vulnerable patients, then the factors
which influence whether or not a supplement is consumed must be identified and efforts made to improve the rate of compliance.

The effect that the ingestion of sip feed supplements has on the consumption of normal foods was not monitored during the feasibility study, but the results of the 24 hour dietary recall assessments made during the long term study indicated that nutritional intake from normal foods was not adversely affected. The results suggested that the ingestion of supplements may even lead to an increase in the nutritional intake from normal foods. The patients who consumed the supplements in the long term study (Chapter 4) had higher intakes of protein and energy on each of the assessment days, than their corresponding pairs of the group who were not offered the supplements. The differences were statistically significant for both of these nutrients at the hospital assessment, even when the nutritional intake derived from the supplements was not included in the analysis.

The 24 hour recall method used to determine nutritional intake can, however, be criticised for its low degree of accuracy and failure to quantify habitual intake. The effect of the consumption of sip feeds on voluntary food intake needs further investigation.

The lack of attention paid to patient compliance to the prescribed nutritional supplementation programme and the effect that supplemental nutrition may have on nutritional intake from normal foods, in the reported literature, is an unacceptable weakness in the design of many trials. As previously discussed (Chapter 4), the authors of the early supplement studies rarely mentioned these two factors, if indeed they were addressed at all. In the well designed naso-gastric feeding study of women admitted to hospital with a fractured femur (Bastow et al., 1983a) both compliance and the effect on voluntary food intake were monitored and reported. In
this study of overnight tube feeding, the 50 out of 64 patients (78%) who could tolerate the naso-tube, received an additional 1000 kcal and 28 g protein per night via this method of feeding. This overnight feeding programme resulted in a statistically significant reduction in day time voluntary food intake in the group of patients described as "thin" compared with their control group who did not receive the supplemental feeding. In the recent large geriatric dietary supplemental feeding study of Larsson et al., (1990) 39 (17%) of the 236 patients who were originally offered the supplement refused to take the supplement and were withdrawn at the onset of the trial. A major criticism of this study is that no mention was made as to what proportion of the 400 mls (400 kcal, 16 g protein) supplement offered was actually consumed by patients who accepted the supplement. Perhaps somewhat surprisingly, in the recently reported study of dietary supplementation following surgical repair of a fractured femur, 27 patients received a daily oral nutritional supplement of 250 mls (254 kcal, 20 g protein) and the claim was made that "the supplement was well tolerated and completely ingested" (Delmi et al., 1990). It is difficult to assess the accuracy of this claim as no description of the method used to assess compliance was given in the paper and quantitative data on the amount of supplement consumed was given. In a sub-group of seven of the patients who were receiving the nutritional supplements and 9 of the non-supplemented patients, a weighed dietary survey of all foods eaten at every meal was performed over a 12 days period during the post-operative course. It was concluded that "supplementation did not reduce the voluntary oral intake". However, the criteria used to select this sub-group of patients was not stated, without which it is difficult to judge the validity of these results.

Therefore, from the recently reported literature there is an impression that oral sip feed supplements are: (1) readily accepted by the majority of elderly patients, (2) consumed in total, and (3) do not result in the suppression of
appetite for normal foods. However, these impressions do not appear to be supported by quantitative data and are, in some respects, in conflict with the investigator's own experience. Further work is clearly indicated.

### 5.1.1 Acceptability of nutritional supplements

No doubt there will always be a place for the provision of oral supplements to hospitalised patients as a way of improving nutritional intake with a minimum of cost in terms of finance and effort. However, the successful and efficient utilisation of such supplements requires them to be sufficiently acceptable to the patients so that reasonable volumes can be consumed on a regular basis. Several studies have been designed with the aim of assessing the relative palatability and acceptability of different supplements, but the clinical value of these has often been limited because the patients (or controls) have made a judgement based upon the tasting of a single small sample of each product. This is obviously not representative of a clinical situation and the results cannot be extrapolated to long term acceptability. Interestingly, in a double blind randomised tasting of 10 ml samples of six commercially available products, the 47 hospital patients registered fewer overall "dislike" responses (33% vs 52%) and more "like" responses (54% vs 33%) than the 48 controls (p<0.05) (Auty et al., 1983). It could be argued that this may have been due to the patients' anxiety to please the researcher, or that hospitalised patients may more readily accept unusual substances. Although one product was most strongly favoured by both patients and controls (Build-Up), it is likely that the provision of a single product on a continuous basis would result in taste monotony becoming a problem. In a similar taste study involving nine flavours of the same product, tasted by 20 patients with non-malignant conditions and 16 control subjects, sweet flavours were preferred to savoury, with chocolate, strawberry and banana being the favourites (Fuller et al., 1985). However, the fact that all supplements were served at room temperature, including
the savoury flavours, may have had some influence on the relative dislike of the savoury flavoured supplements.

It is also recognised that there are changes in taste threshold with ageing and with certain medical conditions or their treatment, which may affect acceptability. All of these can apply to the elderly hospitalised patient. It would seem logical that in order to optimise compliance, a selection of flavours should be offered to the patient permitting them to make a personal choice and to have variety if they wish, so decreasing flavour fatigue. However, experiences from the long term study (Chapter 4) suggest that there is far more to compliance than flavour.

5.1.2 Compliance to medical regimens

The problem of poor compliance has long been recognised and several attempts have been made to relate various demographic, social and psychological variables, as well as severity of illness, to rates of compliance. In 1970 a review of the literature was performed to investigate the factors which influence compliance to medical regimens (Marston, 1970). This paper concluded that demographic variables such as age, sex, socio-economic status, education, religion, marital status and race, when examined apart from other variables, have rarely been predictive of compliance with medical recommendations. It also emphasised the fact that it is not usually appropriate to compare compliance rates from different studies because the results will reflect the methods used to collect the data. The literature published at that time did not support any evidence of an association between severity of illness and compliance behaviour, however an increasing number of medical recommendations was found to be associated with increasing non-compliance and the longer the patients were under treatment, the less likely they were to comply. The findings of this review concluded that knowledge per se regarding the illness and its treatment did not necessarily lead to compliance although Williams et al (1967) reported a positive correlation between knowledge regarding diabetes mellitus and
the degree to which patients adhered to medical advice. The patient-physician relationship, the therapist's individual style of consultation, and the therapist's perceived attitude towards the effectiveness of the drug therapy, were all thought to exert influences on patients' responses to individual drug regimens. However, the overall conclusion was that factors which affect compliance are not simple to determine.

5.1.3 Compliance to dietary regimens
A review of the prevalence and reasons for poor compliance to dietary regimens concluded that patient non-compliance with dietary regimens was at least as frequent as for medical regimens (Glanz, 1980). Dietary regimens differ in fundamental ways from medical regimens for acute conditions and chronic illness. Firstly they are usually restrictive in nature, whilst medication regimens are additive; secondly, diets are usually employed as a method of control of a chronic condition but not a cure. Even in conditions such as diabetes mellitus, where diet is recognised as part of the therapeutic management, studies suggest that only 50% of diabetics fully adhere to their prescribed dietary programme (Holland, 1968; Hulka et al., 1975). Despite being fully aware of the consequences, some diabetic patients have been known to die as a direct result of non-compliance to their insulin regimen (personal communications). If compliance is poor in an existing and life-threatening condition, it would perhaps be expected to be less so in treatments aimed at prevention. The adherence to diets aimed at reducing fat intake in people with risk factors for heart disease has been summarised as ranging from 13-76% (Glanz, 1980), although part of this variation may be accounted for by differences in methodologies. Adherence to cholesterol reducing diets has been reported as being improved by educational interventions such as the provision of a patient booklet and follow up telephone call (Buller, 1978), mass media and intensive instruction (Stern et al., 1976), a high school cardiovascular nutrition course (Podell et al., 1978) and encouraging family participation (Witschi et al.,
1978). It is perhaps understandable why compliance to diets is low in conditions where the patient perceives no direct benefit, or even notices any change by adherence. However, the success rate of weight reducing diets, where the results are immediately apparent, is also low. In general less than half of the patients remain in treatment programmes for obesity (Garb and Stunkard, 1974; Seaton and Rose, 1965), and less than 20% have been reported to sustain weight loss over a number of years (Glennon, 1966; Sohar and Sneh, 1973). In some studies an increased knowledge has been associated with increased compliance (Morse and Sims, 1977; Podell et al., 1978; Stern et al., 1976; Stone, 1961).

5.1.4 Factors which influence compliance

The factors affecting compliance to enteral nutritional supplements have been poorly studied. A compliance trial was conducted in a group of 50 cancer patients to assess the adherence to canned nutritional supplements (Larsen et al., 1983). The subjects were asked to consume two cans of vanilla 1.5 kcal/ml nutritional supplement (total volume and commercial name not stated) for 28 days. Each patient was asked to complete a questionnaire regarding their nutritional well-being and their health beliefs. Twenty-five patients were given an education programme which discussed the benefits of consuming the supplement and explained the role of nutrition in the treatment of cancer. All subjects were requested to taste the supplement and rank it on a nine point hedonic scale. Information regarding the subject's educational status and percentage weight loss since onset of illness were also collected. Compliance was assessed by three methods; daily dairies, can count and verbal self-reporting of intake. The results demonstrated that consumption patterns varied greatly among subjects and that intake did not differ significantly between those who attended the education programme and those who did not. Health beliefs regarding the seriousness of disease, susceptibility to the disease, and the effectiveness of the supplements in preventing, delaying or curing the
disease, did not correlate with intake. Taste score, level of education or percentage weight loss were not associated with the amount of supplement consumed and the authors concluded that, in this group of cancer patients, "intake of nutritional supplements appeared to be an individual response". Whether the same would be true of the elderly female patients admitted to hospital for orthopaedic hip surgery has not been established.

The elderly population, by nature, are likely to be prescribed more medications than the younger population and when a prescription is written the physician generally expects that the patient will use the drug as directed. However, a home study of 111 elderly subjects (59% of whom were female) revealed that 48 subjects (43%) did not take their medication as directed (Cooper et al., 1982). Most of the non-adherence was intentional, with 90% being categorised as under use. The most common reason, given by 25 (52%) of the subjects, was that the patient did not believe that the drug was needed in the dose prescribed by the Physician and, perhaps surprisingly, relatively few, 7 (15%), indicated that side effects were the cause of under-dosing. When comparing all subjects who were non-adherent with all subjects who followed directions, no difference was found between the total number of drugs used, age, level of education, race, sex, income, living alone or number of medical disorders (p>0.10 in all comparisons). However, the intentionally non-adherent subjects were more likely to use more than one pharmacy and receive prescriptions from more than one physician, than the group who were unintentionally non-adherent or the group who followed direction. The motivation to take a prescribed drug may depend upon a person's decision-making process and it was suggested (Cooper et al., 1982) that the intentionally non-adherent subjects may use more than one physician and pharmacy to enhance individual control. In this study, no reference was made to the extent of the patient's knowledge of their condition or benefits of treatment, therefore it was not possible to
assess the relationship between health belief and motivation to comply to medical advice.

5.1.4.1 The influence of attitudes and beliefs

During the past 25 years, a number of conceptual models have been proposed in an attempt to explain the health-related behaviours of an individual. Among these is the "health belief model", the basic components of which are derived from established psychological and behavioral theory, and the elements of which are the individual's perceptions of the condition according to the following categories: susceptibility to the illness; its potential for causing harm and interfering with social functioning; belief in the efficacy or value of a behaviour in reducing threat; and estimates of the physical, psychological and financial costs involved in the proposed action. The model has now been reformulated and expanded to include the categories of health motivation, feelings of control over health matters, faith in doctors and medical care and intention to comply (Becker and Maiman, 1977). For groups such as children and elderly living under the care and supervision of others, it is the relevant health beliefs and attitudes of the carers which are often the primary determinants of the degree to which the dependent patients follow a treatment programme. However, it should be remembered that the majority (96%) of the elderly men and women in the UK are not in hospitals, nursing homes or similar care establishments, but are still living in the community (Davies, 1990) and are therefore in control of their own behaviour.

A recent review of the self-administered use of nutritional (vitamin or mineral) supplements in the free living elderly population of America (Cotugna, 1989a) concluded that the level of education, age and socio-economic status did not have an impact on supplement use by the elderly, although in the general population there was an association. One factor which did appear to be significant was gender, with women being more
frequent users of nutritional supplements than men. This could suggest that female patients may be more likely to comply to a supplement regimen than male patients, although the factors influencing compliance in hospital patients may be very different from those influencing the free living elderly. Since demographic variables do not appear to differentiate between those who take nutritional supplements and those who do not, the role of attitudes and beliefs may be important and may offer some insight into why some patients comply to regimens directed by a physician whilst others do not. Attitudes and beliefs are associated with knowledge and behaviour.

In a recent study, 195 residents (76% female) of four federally subsidised senior citizen apartment complexes in California were interviewed using a 62-item instrument containing demographic questions and questions about supplement use (Cotugna, 1989b). The aim was to measure attitudes, intention, behavioral beliefs, outcome evaluations, normative beliefs, and motivation to comply to supplement use. The results indicated that the beliefs which most strongly predicted a positive attitude towards taking nutritional supplements were that supplements would improve health and not be a waste of money. If this was translated to the hospital environment, it would seem that the role of education should emphasise the benefits of nutritional supplementation and the fact that the cost of the supplements will not have to be paid by the patient. The residents of the apartment complexes are likely to be from similar social and economical backgrounds and would have elected to live in a similar environment. In contrast, the hospital patient population is likely to be extremely diverse in terms of social, economical and geographical situations. Different subgroups may have different attitudes and beliefs.

Since the elderly appear to be receptive to nutritional information, it was considered that compliance to nutritional supplementation in an elderly hospital population might be improved by providing nutritional education
which informed the patient of the role of nutrition in recovery. This was one of the aims of the present study.

When the attitudes of rural and urban elderly, concerning supplement use, were compared by two questionnaires, 70% of the rural elderly and 90% of the urban elderly reported using nutritional supplements. The most commonly purchased supplement in the rural group was calcium, compared with multivitamins in the urban group (Betts and Rezek, 1989). The first questionnaire included demographic questions, an attitude scale and the questions concerning supplement purchases and sources of information about nutrition. The second questionnaire contained an advertisement about calcium supplements followed by questions regarding means to "improve calcium" and health concerns. The questionnaires revealed some interesting results between the two groups. The rural elderly had a significantly lower mean education level and a significantly higher number of misconceptions. The main sources of information for both groups were the media (particularly magazine articles and television and newspaper advertisements), physicians, family and friends, and registered dietitians. In response to the calcium advertisement, 30% of those interviewed stated they would be unlikely or would never take a calcium supplement to improve calcium intake, but 86.7% stated they would take calcium supplements to prevent health problems. It should be noted that 53% said they were already taking a calcium supplement, even though 51.7% felt that there could be dangers associated with taking calcium supplements. These contradictions in the responses may indicate that the elderly are susceptible to advertisements which imply that supplements are needed to prevent health problems. When the subjects were asked what actions they would take to improve calcium intake, the most common replies were to increase milk and cheese consumption. These results indicate that the elderly do have an ability, and a desire, to assimilate nutritional information and therefore, if accurate and reliable information could be provided to patients
whilst they were in hospital then this may be a means of improving compliance to sip feed supplements.

More recently the relationship between beliefs about nutrition and dietary practices of the elderly has been studied by interviewing 424 non-institutionalised individuals aged 58-100 years living in the Houston metropolitan area (McIntosh et al., 1990). Sixty-seven percent of those interviewed used a nutritional supplement of some description, although (with the exception of Vitamin B<sub>6</sub>) magnesium and fibre, the nutrient density (amount of nutrient per 1000 kcal) did not differ significantly between the user and the non users. In contrast to the findings of other workers, attitudes towards the use of nutritional supplements, health foods, and/or nutritional quality of conventional foods was found to differ with age, sex and education level. Women were more likely to believe in nutritional supplements, and take them, than were men; elderly men believed more strongly in the nutritional quality of ordinary foods, and better educated subjects and elderly subjects with a higher income were sceptical about the importance of health foods, although they were equally as sceptical about the nutritional value of ordinary foods. Nutrient intake was found to be higher in those with more positive feelings about nutritional supplements, which could be due to an increased awareness of diet and health. It is suggested by the authors that nutrition education should be targeted to include the issues which are of interest to the group and that topics such as the role of nutrients in disease prevention and appropriate nutritional supplementation should be explored. If the same theory applies to hospital patients it would appear that a nutrition education programme directed towards the role of nutrition in wound healing would be appropriate.

5.1.4.2 Knowledge and the effect of nutrition education on compliance
It is almost 20 years since the American Blue Cross Association recognised the importance of nutritional education and produced a white paper proposing guidelines for patient education programmes. The paper emphasised that patient education should encompass components of total patient care (Blue Cross, 1974). Five years later a study was published which assessed the effect of a teaching programme on knowledge and compliance of cardiac patients (Linde and Janz, 1979). A secondary aim of this study was to evaluate whether nurses were effective health care educators. A total of forty-eight cardiac patients were included in the study, 25 being taught by Masters-prepared clinical specialists and 23 by nurses with less than Masters preparation. The six teaching sessions were provided on an individual basis, each lasting 20-25 minutes and the course included information on the disease process and surgical intervention, activity progression, medication and dietary regimens. Findings included significant changes in knowledge scores from the preoperative test to the discharge test and stability in most scores from discharge to two post discharge visits (one month after discharge and then three to four months later). Compliance to the advice given was measured in four ways, patient reports on reduction in risk factors, laboratory follow-up results, adherence to dietary recommendations and attendance at out-patient clinic appointments. Compliance percentages were reported to be significantly higher than those for cardiac patients in previous studies, suggesting that nutrition education was effective. The study also showed that although staff nurses could influence patient knowledge, the Master-prepared specialist nurses had a much greater impact on patient learning. Similarly, a study of sixty-seven psychiatric inpatients also demonstrated that patient education, involving explanations of the nature of the disorder and pharmacological management, can have a positive effect on compliance following their discharge from hospital. After five months, the group who had been involved in the education programme showed an outpatient non-compliance rate of only 9% as compared with 66% in the group who did not
receive the programme. Clearly education can improve compliance and it would seem logical to assume that this has been as a result of reinforcing the positive benefits of compliance to medical advice. However, the relationship is more complex, as illustrated by the observation that it was the reduction in the level of the patient's fears of drug addiction and side effects that were instrumental in improving compliance (Seltzer et al., 1980). In the case of nutritional intervention, where side effects are extremely unlikely to be a cause of concern, other influences must prevail. This study also reported that poor compliance was related to living alone, a situation found in a large proportion of elderly female patients who are admitted to hospital for orthopaedic surgery.

A study has recently been conducted to examine the relationship between a nutrition education programme and nutrition knowledge and eating behaviours in adults aged 60-88 years (Bedell and Shackleton, 1989). This study involved twenty-nine subjects (4 male and 25 female) and was conducted in a Community Centre in New York. The subjects were randomly assigned to an experimental (n=15) or control (n=14) group. The experimental group attended a series of nutrition teaching sessions, each lasting 45 minutes with a 15 minute question and answer period at the end. The topics addressed were the basic food groups, nutrients, food and the ageing process, and consumer issues. A 25-item true/false questionnaire was administered before and after the course, and a 24 hour dietary recall interview was performed. The results were used to assess baseline nutrition knowledge and eating behaviours, as well as to evaluate cognitive gain and behavioral change in relation to course aspects. Analysis of the results revealed no significant increase in nutrition knowledge and positive eating behaviour in the experimental group, although a trend towards improvement in both aspects was noted. The reasons for lack of change could be because, at the age of 60 years, individuals have perceived ideas about nutrition and established eating patterns based on a lifetime of
experiences and influences. Such subjects may not readily accept change. If a medical condition were diagnosed, subjects may then become more open to receiving advice and making decisions as to whether to accept the advice or not. In this situation, other factors must influence the decision making process.

In a study of 396 Mexican-American families, interviews, questionnaires and sentence completion tests were used to identify the variables which were involved in the parental decision to adopt or reject the physicians' proposed medical/surgical procedures for their child's cardiac problems (Toledo et al., 1979). It became apparent that those parents who complied to the physicians' advice trusted the doctor's judgement over their own, whereas those parents who did not comply with the physicians advice, did not. In many cases, the compliant parents did not understand the need for the procedures, but went ahead with the advice because "the doctor said so". This highlights not only that patients (or, in the case of children, their families) may have little knowledge or understanding about their condition or the benefits of treatment, but also that the patient-physician relationship is an important factor in influencing compliance. The development of a close relationship and rapport was considered crucial in bringing about feelings of confidence in the physician's expertise and, subsequently, confidence in following his recommended treatment plan.

The theory of the importance of rapport between patient and health-carer, and confidence in the knowledge of the health carer can presumably be applied to the elderly orthopaedic patient admitted to hospital. If this is so, an education programme taught by a specialist in nutrition and dietetics, in conjunction with daily visits to build on the relationship, could be an effective way of improving compliance to a sip feed supplementation programme. It would also be useful to assess whether attitudes and beliefs are important determinants of compliance in this patient population, and
whether these factors could be mediated by a nutrition education programme.
5.2 AIMS OF THE STUDY
The primary aims of this study was to evaluate the effectiveness of a basic nutrition education programme, presented to both patients and nursing staff, on the compliance to a sip feed supplement, and to identify the factors which are associated with non-compliance.

The secondary aim of the study is to evaluate whether the consumption of the nutritional supplement has an effect on the nutritional intake from normal foods.
5.3. **SUBJECTS AND METHODS**

This study was carried out on the two orthopaedic wards (Bramshott and Ewhurst) of the Royal Surrey County Hospital (Guildford) between January and May 1990. Ethical committee approval was obtained from the hospital Ethics Committee. The purpose of the study was explained to all eligible patients and they were then given an opportunity to ask questions and consider participation before verbal informed consent was obtained.

### 5.3.1 PATIENTS

During the recruitment period of 4 months, it was anticipated that approximately 40-50 eligible patients would consent to take part in the study, the aim being that a minimum of 20 patients would be recruited from each of the two wards.

**Inclusion criteria**

1. Female.

2. In 60th year of age, or above.

3. Admitted for elective (hip or knee joint replacement) or emergency (repair of fracture) orthopaedic surgery.

4. Nutrition Risk Score $\geq 7$, obtained by completion of the Nutrition Risk Questionnaire (NRQ).

5. Consent to participate.

**Exclusion criteria**

...
1. Mental impairment (temporary or permanent) which may hinder communication or compliance.

5.3.2 **EXPERIMENTAL DESIGN** (Figure 5.1)

The outline protocol of this study, the structure and format of the nutrition education programme and the simple "Nutrition and illness" questionnaire were designed by the author of this thesis. The day-to-day running of the study and the patient assessments were carried out with the assistance of two co-researchers [BSc (hons) Nutrition] students who had successfully completed their practical training for State Registration in Dietetics and who were using this data for their final year projects (*Bisson, 1990; Blades, 1990*). Regular meetings were held between the two students and the author to update on progress and to make decisions as appropriate.

The ward was visited every day so that, where possible, the patients were interviewed on the day of admission. In the case of emergency admissions, patients were interviewed within 48 hours of surgery.

Prior to the initial interview, the hospital notes were used to document general information including age, medical history, social background and current medication. This was then used in conjunction with the initial patient interview to complete the NRQ. For those patients who fulfilled the entry criteria a "Nutrition and Illness" attitude questionnaire was completed and anthropometric variables were measured.
Fig 5.1 Recruitment and categorisation of patients into the Nutrition Education Programme.
5.3.2.1  "Nutrition and illness" Questionnaire
This questionnaire was developed as a result of experiences gained from the close patient contact obtained during the long term follow up study and after a review of the literature in relation to compliance. The questionnaire comprised ten questions which were read to the patient by one of the investigators. The questions numbered 1, 2, 3 and 4 were aimed at investigating the patient's interest and awareness in the general topic of nutrition; questions 5 and 6 were aimed at assessing the individual's specific knowledge regarding, and attempts to meet, their nutritional requirements; questions 7 and 9 were aimed at assessing the patient's attitude towards their general health and life to date; and questions 8 and 10 attempted to evaluate the patient's attitude towards their ability to cope once they got home and their future outlook. For each question there are five possible responses to choose from, which were scored from 5 to 1 (from left to right), the higher scores reflecting a greater awareness or more optimistic outlook. A copy of the questionnaire can be found in Appendix V.

5.3.2.2  Anthropometric assessments
The following assessments were made on admission, 72 hours post operatively and immediately prior to discharge:

1. Body weight
   In the case of patients admitted for elective hip or knee surgery, this was measured by the nursing staff on the ward chair scales; for the emergency admissions, the patients were asked to self-report their current weight.

2. Mid upper arm circumference (MUAC)
3. Triceps skinfold thickness (TSF)
4. Percentage body fat, measured using the Futrex 500, a computerised system based on infra-red interactance.

Further details of these techniques are given in Chapter 2 (Methodology).

5.3.2.3 Clinical assessments
Duration of hospital stay was recorded (total days from admission to discharge).

5.3.2.4 Nutritional and dietary assessments
Two days after surgery, a dietary history was taken by an experienced co-investigator and each patient was asked to consume the nutritional supplement for their duration of hospital stay. A chart was given to the patient and they were asked to record each time that a complete carton of the sip feed supplement was consumed. This was the day that the patients were first offered the supplement and was considered Day 0. On Day 1 the three day detailed food intake assessment was explained to the patient, and was conducted on Days 2, 3 and 4. Immediately before patients were recruited into the study, average food portions were weighed from the ganymede belt in the hospital kitchen. During the three day food intake assessment, the patients retained their hospital menu cards, and the food remaining on their plate at the end of each meal was weighed. The weight of wasted food was deducted from the average food portion weight, and the difference was regarded as being the amount consumed. This was then entered onto a Compeat software programme (Lifeline Nutritional Services Ltd) and used to calculate nutrient intake. Patients were also visited every day during this period to ascertain whether any additional food was consumed in the form of snacks. At the end of this three day period a further 24 hour dietary recall was performed in order to compare the results obtained from the two methods. If the patient was in hospital for
longer than 14 days, then a second 2-day detailed food intake assessment was performed.

5.3.2.5 The nutritional supplement
One product, Fortisip (Cow & Gate Ltd) was chosen as the supplement which would be offered to the patients in this study. The main reasons for this choice were a) the variety of flavours (banana, orange, tropical fruits and vanilla) and, b) the packaging (a ready to use tetra-pack similar to commercially available snack drinks) which meant that the supplement could be either drunk directly from the pack through a straw, or poured into a glass. The supplement was nutritionally complete and contained 300 kcal in each 200 ml pack. Details of the nutritional composition are presented in Table A5.1, Appendix V. It was emphasised to all the patients that the supplement should be taken as an additional beverage and not as a replacement for normal foods.

5.3.2.6 Nutrition Education Programme (NEP)
Patients who were admitted to Bramshott Ward and who fulfilled the entry criteria received a short nutrition education programme, on a one-to-one basis. All of the staff of Bramshott Ward were invited, and encouraged, to attend a series of four nutrition lectures. The staff lectures were repeated at regular intervals throughout the study period to give most of the staff an opportunity to attend all four lectures. The patients and staff on Ewhurst Ward received no nutritional education.

5.3.2.6.1 Nutrition Education Programme (NEP) for ward staff
The staff of Bramshott Ward were all invited to attend four lunch-time nutrition education lectures, each lasting approximately 30-40 minutes with an additional 10-15 minutes for discussion. All staff were encouraged to
attend by the Ward Sister. The first series of four lectures was given by the author of this thesis and repeated lectures were given by a co-investigator. A brief description of the content of each of these lectures is given below:

1. **Dietary supplements: The Royal Surrey County Hospital Study**
   Results of the feasibility study and preliminary findings of the long term study were summarised, with the emphasis being that the provision of nutritional supplements can prevent loss of body fat and muscle. The problem of compliance was discussed and the objectives and trial design of the compliance study were outlined.

2. **How do you recognise a nutritionally at risk patient?**
   A brief summary was given of the objective methods available to identify a malnourished patient, particularly those methods commonly used in research (ie: anthropometric, biochemical and clinical outcome parameters). However, attention was focused on the ability to detect subtle malnutrition, and identifying vulnerable patients who may develop malnutrition whilst in hospital. The nurse was presented as having a key role to play in the identification of such patients. This was not only because of their clinical knowledge, but also the fact that a close relationship exists between nurse and patient. In addition, the nurse is in an ideal position to detect potential problems at a very early stage because of frequent contact. The concept of the NRQ was discussed as a very quick and simple means of screening all patients during the admission procedures.

3. **How can specialised feeding aid the convalescing patient?**
   The prevalence of hospital malnutrition, its causes and consequences were discussed. Examples of the benefits which can be obtained by the provision of nutritional support were presented, using specific
studies which have been reported in the literature (Eg: Mullen et al., 1980). The advantages and disadvantages of the current methods available were discussed, and the nurses were encouraged to consider which methods would be appropriate in which situations.

4. Special nutritional problems of the elderly orthopaedic patient
Some background information regarding the increasing number of elderly people in the population and the observation that malnutrition is still found in the elderly living in the community was presented. Some of the reasons for this were discussed in an attempt to raise awareness of the fact that these patients may have had a poor nutritional intake for many years. The lecture then became focused on the specific requirements of the elderly surgical patient, particularly the role of nutrition in wound healing and convalescence.

In conjunction with the series of lectures, the nurses were provided with a written summary to which they could refer in the future. These hand-outs, copies of which can be found in Appendix V, were also given to those nurses who were unable to attend all four of the series of lectures.

5.3.2.6.2 Nutrition Education Programme (NEP) for patients
On Day 0, the patients on Bramshott ward were visited by a co-investigator and approximately 30 minutes were spent initiating a short education session. Each patient was then involved in a one-to-one discussion, during which the following topics were discussed:

1. Basic introduction to the study and tasting of the nutritional supplements.
2. An introduction to the basic food groups (protein, fats, sugars, fruit and vegetables, cereals, liquids).
3. The importance of an adequate food intake during hospitalisation.
4. The role of the supplements in aiding recovery (at this point the patient was asked to consume two cartons of Fortisip per day).
5. The patient was then shown how to complete the chart recording supplement consumption.
6. Finally the patient was offered a tasting session in order to determine which flavours they preferred. If desired, the supplement could be offered chilled.

On Day 1, the patient was visited again to ask whether they had any questions about the information they had received on the previous day, and about 15 minutes was spent explaining the method of the detailed weighed food intake assessment.

The patients on Ewhurst Ward were simply offered the supplements, with minimal encouragement to take them and did not receive any of the verbal or written nutritional information. The information they were given regarding the detailed food intake assessment was the same as that received by the patients on Bramshott Ward.
5.4 STATISTICAL ANALYSIS AND PRESENTATION OF RESULTS

Comparisons of admission data (age, type of admission and NRS) were made between the sub-group of patients who received the NEP and those who were not offered the NEP. Patients from both groups were then categorised as "Compliant" if they consumed at least one carton of the supplement each day and "Non-Compliants" if they consumed only a few sips or refused to take the supplement at all. Results are presented for the sub-group of patients who were considered compliant (C) and comparisons made with the sub-group which were considered non-compliant (NC). Differences between mean group values were compared using unpaired student t-tests. The probability of a difference in the percentages (of admission types and compliance rates) between the two group were compared, was calculated using the paired alternatives statistical test.

Comparisons of the distribution of discrete variables (NRS responses) in one sample with the distribution of the variables in another sample were made using the Chi-squared test. Differences were considered to be significant at the P<0.05 level.
5.5 RESULTS

5.5.1 Recruitment of patients and admission characteristics
Throughout the four month inclusion period a total of 25 eligible patients were recruited into this trial and their progress followed until discharge from hospital. Of these 25 patients, 14 were recruited from Bramshott Ward and therefore underwent the Nutrition Education Programme (NEP), whilst 11 were recruited from Ewhurst Ward and received no detailed nutritional advice. Of the 25 patients, 10 were emergency admissions for repair of a hip fracture and 15 were admissions for elective surgery (13 hip replacements and 2 knee replacements). The admission characteristics (age, type of admission and NRS) of the patients are presented in Table 5.1. There were no statistically significant differences in age or NRS between the patients receiving the NEP (Bramshott Ward) and those who were not offered the NEP (Ewhurst Ward). However there was a significantly higher percentage of elective admissions to the Ewhurst ward which was not offered the NEP (p<0.05). Further details of the patients in this study can be found in Appendix V.
Table 5.1  Summary of admission characteristics (age, type of admission and NRS) expressed as the total group of patients studied, and sub-divided into the group who received the NEP and those who were not offered the NEP.

<table>
<thead>
<tr>
<th>Admission Characteristic</th>
<th>Total (n=25)</th>
<th>Patients receiving NEP (Bramshott Ward, n=14)</th>
<th>Patients not offered NEP (Ewhurst Ward, n=11)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>71.5 (± 7.1)</td>
<td>70.6 (± 8.3)</td>
<td>72.6 (± 5.4)</td>
</tr>
<tr>
<td>Type of admission</td>
<td>Emer = 10 (40%) / Elec = 15 (60%)</td>
<td>Emer = 7 (50%) / Elec = 7 (50%)</td>
<td>Emer = 3 (27%) / Elec = 8 (73%) *</td>
</tr>
<tr>
<td>NRS</td>
<td>9.7 (± 2.8)</td>
<td>10.1 (± 2.8)</td>
<td>9.2 (± 2.8)</td>
</tr>
</tbody>
</table>

Results for age and NRS are expressed as mean values (+ sd)

* p<0.05 between the two groups.

5.5.2 The effect of the Nutrition Education Programme (NEP) on compliance to the supplement (Fortisip).

The numbers of patients categorised as Compliant (C) and Non-Compliant (NC) in terms of those who had received the NEP, compared with those who were not offered the NEP, are presented in Table 5.2. Of the total 25 patients studied, 11 (44%) were regarded as compliers and 14 (56%) were regarded as non-compliers. Of the 14 patients who received the NEP, 7 (50%) were regarded as compliant, compared with 4 (36%) of the 11 patients who were not offered the NEP. The difference in compliance rate between
the group who received the NEP and the group who did not, did not reach statistical significance.

Table 5.2 **Comparison of compliance rates between those patients receiving the Nutrition Education Programme (NEP) and those who were not offered it.**

<table>
<thead>
<tr>
<th></th>
<th>Patients receiving NEP (n=14)</th>
<th>Patients not offered NEP (n=11)</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compliant (C)</td>
<td>7 (50%)</td>
<td>4 (36%)</td>
<td>11 (44%)</td>
</tr>
<tr>
<td>Non-Compliant (NC)</td>
<td>7 (50%)</td>
<td>7 (64%)</td>
<td>14 (56%)</td>
</tr>
<tr>
<td>Totals</td>
<td>14</td>
<td>11</td>
<td>25</td>
</tr>
</tbody>
</table>

*Results are presented as absolute numbers of patients, with percentages in brackets.*

There were no significant differences in compliance rates between the group who received the NEP and the group who were not offered the NEP.
5.5.3 Compliance in relation to age, type of admission and response to the NRQ.

The compliant group had a mean age of 70.7 (± 8.0) years, compared with a mean age of 72.1 (± 6.5) years in the non-compliant group. This difference was not statistically significant (Table 5.3).

Of the sub group of 10 patients admitted as emergency cases (for repair of fracture of the hip), 6 (60%) were regarded as compliers compared with 5 (33%) of the 15 patients admitted as elective cases (a planned hip or knee replacement). This difference was not statistically significant.

Table 5.3 Summary of admission characteristics (age, type of admission and NRS) expressed as the total group of patients studied, and sub-divided into the Compliant and Non-Compliant sub-groups.

<table>
<thead>
<tr>
<th>Admission Characteristic</th>
<th>Total (n=25)</th>
<th>Compliant (n=11)</th>
<th>Non-Compliant (n=14)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>71.5 (± 7.1)</td>
<td>70.7 (± 8.0)</td>
<td>72.1 (± 6.5)</td>
</tr>
<tr>
<td>Type of admission</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emer = 10 (40%)</td>
<td>Emer = 6 (60%)</td>
<td></td>
<td>Emer = 4 (40%)</td>
</tr>
<tr>
<td>Elec = 15 (60%)</td>
<td>Elec = 5 (33%)</td>
<td></td>
<td>Elec = 10 (66%)</td>
</tr>
<tr>
<td>NRS</td>
<td>9.7 (± 2.8)</td>
<td>9.4 (± 2.7)</td>
<td>10.0 (± 3.0)</td>
</tr>
</tbody>
</table>

Results for age and NRS are expressed as mean values (+ sd)

There were no significant differences between the Compliant and Non-Compliant groups for any of the admission characteristics reported.

The mean Nutrition Risk Scores (NRS) obtained in response to the completion of the NRQ were not significantly different between the
Compliant (mean NRS 9.4 ± 2.7) and the non-compliant (mean NRS 10.0 ± 3.0) groups. In the NC group there were a greater number of patients who lived alone, ate alone, relied on others to get shopping, drank less than 3.5 pints of milk each week and suffered from bronchitic disease, compared with the C group although Chi-square test calculated that these differences were not statistically significant. These results are presented in Table 5.4. A copy of the NRQ can be found in Appendix II.
Table 5.4  Comparison of mean NRS and some responses to the NRQ between the compliant and non-compliant groups.

<table>
<thead>
<tr>
<th>NRQ Statement</th>
<th>Number of patients with positive response</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Compliant (n=11)</td>
</tr>
<tr>
<td>Lives alone</td>
<td>4</td>
</tr>
<tr>
<td>Eats alone</td>
<td>2</td>
</tr>
<tr>
<td>Relies on others to get shopping</td>
<td>2</td>
</tr>
<tr>
<td>Drinks &lt; 3.5 pints of milk per week</td>
<td>6</td>
</tr>
<tr>
<td>Bronchitic disease</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total mean NRS (± sd)</strong></td>
<td><strong>9.4 (± 2.7)</strong></td>
</tr>
</tbody>
</table>

There were no significant differences between the Compliant and Non-Compliant groups in relation to the mean NRS, or the number of patients with a positive response for questions above.

5.5.4 Results of the "Nutrition and illness" questionnaire

The "Nutrition and Illness" questionnaire was completed for all 25 patients. Of the 250 responses, there was one "don’t know" reply (patient 14, question 6). For the purpose of analysis, this was given a score of 3 (mean of 1-5 possible responses). The total score of each individual patient was calculated by summing the scores for the 10 questions. The responses were then analysed in relation to the four categories of questions as defined above (5.3.2.1 Experimental design). The results have been presented for the four sub-groups so that comparisons can be made between the patients.
receiving the NEP and those who were not offered the NEP, and between the compliant (C) and the non-compliant (NC) groups (Table 5.5). The individual patient scores are presented in Appendix V, Table A5.2

There were no significant differences between the group receiving the NEP and the group who were not offered the NEP, in the group mean scores, whether expressed in relation to total scores or sub-divided into the four "attitude" categories as described above. When the scores of the compliant patients were compared with those of the non-compliant patients, there were no significant differences in either total score, or scores obtained after sub-dividing into the four "attitude categories".
Table 5.5 Comparison of scores obtained from the "Nutrition and Illness" questionnaire.

<table>
<thead>
<tr>
<th>Question number (n=10)</th>
<th>Attitude assessed</th>
<th>Group receiving NEP (n=14)</th>
<th>Group not offered NEP (n=11)</th>
<th>Compliant (n=11)</th>
<th>Non compliant (n=14)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 - 10 Sum total</td>
<td></td>
<td>33 (± 6)</td>
<td>33 (± 6)</td>
<td>35 (± 6)</td>
<td>32 (± 6)</td>
</tr>
<tr>
<td>1, 2, 3, 4 nutrition awareness/interest</td>
<td></td>
<td>12 (± 4)</td>
<td>11 (± 5)</td>
<td>12 (± 5)</td>
<td>11 (± 4)</td>
</tr>
<tr>
<td>5, 6 Nut Req't</td>
<td></td>
<td>6 (± 1)</td>
<td>6 (± 1)</td>
<td>6 (± 1)</td>
<td>6 (± 1)</td>
</tr>
<tr>
<td>7, 9 Health and life to date</td>
<td></td>
<td>8 (± 2)</td>
<td>8 (± 1)</td>
<td>8 (± 2)</td>
<td>8 (± 1)</td>
</tr>
<tr>
<td>8, 10 Future outlook</td>
<td></td>
<td>8 (± 1)</td>
<td>8 (± 1)</td>
<td>8 (± 1)</td>
<td>8 (± 2)</td>
</tr>
</tbody>
</table>

Results are expressed as mean values (+ sd)

There were no significant differences between any of the four sub-groups, for any of the score sub-totals, or total.
5.5.5 Reasons given by patient for non compliance
Of the 14 patients who were categorised as non-compliers, the most common reason given for not taking the supplement was related to taste or texture. Seven patients reported that they found the supplement too sweet, too sickly or disliked the texture or mouth feel. Several of these patients attributed their rejection to the fact that they did not like milk. Three patients said they could not manage the supplement as well as their normal meals and a further three subjects felt that they did not need the supplement as their appetite was good and they were eating well. One patient rejected the supplement as she felt nauseous at the time of offering, and declined to try the supplement at a later date when the nausea had passed.

5.5.6 Total volume of supplement consumed
All patients were asked to consume as many cartons of the supplement as possible, aiming to consume three cartons (600 mls) daily if possible. Of the 11 patients who complied to the regimen, one patient consumed three cartons per day, seven patients consumed an average of two cartons per day, and three patients consumed an average of one carton per day.

5.5.7 Nutritional intakes of compliant (C) compared with non-compliant (NC) patients.
Comparisons for the mean of the three days of the nutritional intakes (energy, protein, fat and carbohydrate) of 8 of the C and 13 of the NC groups from the hospital "weighed waste" assessments are represented in Figure 5.2, Table 5.6, and the absolute values for the individual days are given in Appendix V, Table A5.3 Results for the Compliant group have been presented as group means for nutritional intakes on Day 1, Day 2, Day 3 and the average of these three days, and for the compliant group have been expressed both with and without the supplement.
Figure 5.2  Intakes of energy, protein, fat and carbohydrate (mean of 3 days) for the compliant, including supplement (C-S), excluding supplement (C-ES) and non-compliant (NC) groups in hospital.

Results are presented as mean values, ± sd represented by the bar.
Values significantly different between groups, compared with NC group; * P<0.05

Table 5.6  Intakes of energy, protein, fat and carbohydrate (mean of 3 days) for the compliant, including supplement (C-S), excluding supplement (C-ES) and non-compliant (NC) groups in hospital.

<table>
<thead>
<tr>
<th></th>
<th>Compliers - Including supplements (C-S) (n=8)</th>
<th>Compliers - Excluding supplements (C-ES) (n=8)</th>
<th>Non Compliers (N-C) (n=13)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ENERGY (Kcal)</td>
<td>2095 * (± 289)</td>
<td>1609 * (± 356)</td>
<td>1251 (± 159)</td>
</tr>
<tr>
<td>PROTEIN (g)</td>
<td>73 * (± 10)</td>
<td>59 * (± 11)</td>
<td>49 (± 5)</td>
</tr>
<tr>
<td>FAT (g)</td>
<td>102 * (± 17)</td>
<td>80 * (± 21)</td>
<td>60 (± 7)</td>
</tr>
<tr>
<td>CARBOHYDRATE (g)</td>
<td>234 * (± 42)</td>
<td>176 * (± 47)</td>
<td>137 (± 28)</td>
</tr>
</tbody>
</table>

Results are presented as mean values (± sd), where n refers to the number of values.
Values significantly different between groups, compared with NC group; * P<0.05
The intakes of all the nutrients assessed were higher in the compliant group than in the non-compliant group, even when the nutritional value of the supplements was not included in the analysis. These differences were statistically significant for all the nutrients when the three days were averaged, and for some nutrients on Day 1 (energy, protein and fat) and Day 3 (carbohydrate), (all p<0.05).

When the nutritional value of the supplement was included in the analysis, to give total nutritional intake in the compliant group, the intake of all nutrients was significantly (p<0.05) higher on all days.

The nutritional intakes calculated from the diet histories taken on admission were not significantly different between the compliant and non-compliant groups (See Figure 5.3, Table 5.7).
Figure 5.3  Normal dietary intake (as assessed by an initial diet history) expressed for the Compliant (C) and Non-Compliant (NC) sub groups.

Results are presented as mean values, ± sd represented by the bar.

<table>
<thead>
<tr>
<th></th>
<th>Compliant (C)</th>
<th>Non-Compliant (NC)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n=8)</td>
<td>(n=11)</td>
</tr>
<tr>
<td>ENERGY (Kcal)</td>
<td>1698 (± 516)</td>
<td>1681 (± 351)</td>
</tr>
<tr>
<td>PROTEIN (g)</td>
<td>71 (± 13)</td>
<td>75 (± 20)</td>
</tr>
<tr>
<td>FAT (g)</td>
<td>74 (± 34)</td>
<td>75 (± 23)</td>
</tr>
<tr>
<td>CARBOHYDRATE</td>
<td>200 (± 90)</td>
<td>185 (± 63)</td>
</tr>
</tbody>
</table>

Results are presented as mean values (± sd), where n refers to the number of values.
5.5.8 Nutritional intakes of the group of patients who received the Nutrition Education Programme (NEP) compared with the group who were not offered the NEP.

The group mean nutritional intakes (excluding supplement) of 11 of the patients who received the NEP compared with 10 of the patients who were not offered the NEP are presented in Figure 5.4, Table 5.8 and the absolute values are given in Appendix V, Table A5.4.
Figure 5.4  Intakes of energy, protein, fat and carbohydrate (mean of 3 days) for the group who received the NEP and the group who were not offered the NEP (N-NEP).

Results are presented as mean values, ± sd represented by the bar.

Table 5.8  Intakes of energy, protein, fat and carbohydrate (mean of 3 days) for the group who received the NEP and the group who were not offered the NEP (N-NEP).

<table>
<thead>
<tr>
<th></th>
<th>Nutritional Education Programme (NEP) (n=11)</th>
<th>No Nutritional Education Programme (N-NEP) (n=11)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ENERGY (Kcal)</td>
<td>1355 (± 355)</td>
<td>1423 (± 245)</td>
</tr>
<tr>
<td>PROTEIN (g)</td>
<td>53 (± 12)</td>
<td>52 (± 6)</td>
</tr>
<tr>
<td>FAT (g)</td>
<td>68 (± 21)</td>
<td>68 (± 11)</td>
</tr>
<tr>
<td>CARBOHYDRATE</td>
<td>143 (± 40)</td>
<td>161 (± 40)</td>
</tr>
</tbody>
</table>

Results are presented as mean values (± sd), where n refers to the number of values.
There were no statistically significant differences in the intakes of any of the nutrients assessed, between the two groups, when calculated from either the "weighed waste" method used in hospital or the diet history method (Figure 5.5, Table 5.9).

5.5.9 Body weight, anthropometry and hand grip strength (baseline values and changes from admission to discharge)

The results of the assessments of body weight, MUAC, TSF, HGS and % body fat are presented in Table 5.10. There were no significant differences on admission between the compliant and non-compliant groups, nor any significant changes from admission to discharge, for any of the parameters assessed.

5.5.10 Duration of stay in hospital (admission to discharge)

The mean duration of stay in hospital was 14.0 (± 4.8) days for the compliant group and 14.3 (± 3.9) days for the non-compliant group (not significantly different).
Figure 5.5 Normal dietary intake (as assessed by an initial diet history) expressed for the group receiving the NEP and the group not offered the NEP (N-NEP).

Results are presented as mean values, ± sd represented by the bar.

Table 5.9 Normal dietary intake (as assessed by an initial diet history) expressed for the group receiving the NEP and the group not offered the NEP (N-NEP).

<table>
<thead>
<tr>
<th></th>
<th>Nutritional Education Programme (NEP)</th>
<th>No Nutritional Education Programme (N-NEP)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n=11)</td>
<td>(n=11)</td>
</tr>
<tr>
<td>ENERGY (Kcal)</td>
<td>1701 (± 379)</td>
<td>1673 (± 460)</td>
</tr>
<tr>
<td>PROTEIN (g)</td>
<td>74 (± 12)</td>
<td>72 (± 23)</td>
</tr>
<tr>
<td>FAT (g)</td>
<td>77 (± 24)</td>
<td>73 (± 31)</td>
</tr>
<tr>
<td>CARBOHYDRATE</td>
<td>191 (± 64)</td>
<td>190 (± 84)</td>
</tr>
</tbody>
</table>

Results are presented as mean values (± sd), where n refers to the number of values.
Table 5.10 Body weight, anthropometry (MAUC, TSF), hand grip strength and percentage body fat of the compliant (C) and non-compliant (NC) groups.

<table>
<thead>
<tr>
<th></th>
<th>BODY WEIGHT</th>
<th>MAUC (cm)</th>
<th>TSF (mm)</th>
<th>HGS (lbs/sq.in)</th>
<th>Body Fat (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Admission</td>
<td>Discharge</td>
<td>Admission</td>
<td>Discharge</td>
<td>Admission</td>
</tr>
<tr>
<td>All Patients</td>
<td>63.3 ± 3.3</td>
<td>65.2 ± 1.5</td>
<td>29.9 ± 3.2</td>
<td>29.3 ± 3.2</td>
<td>32.0 ± 2.5</td>
</tr>
<tr>
<td>(n=25)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Compliant Patients</td>
<td>61.5 ± 2.2</td>
<td>63.1 ± 1.3</td>
<td>29.0 ± 2.2</td>
<td>29.0 ± 2.2</td>
<td>32.9 ± 1.1</td>
</tr>
<tr>
<td>(n=10)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-Compliant Patients</td>
<td>64.6 ± 3.9</td>
<td>67.4 ± 1.0</td>
<td>28.9 ± 3.9</td>
<td>29.5 ± 3.6</td>
<td>32.5 ± 3.0</td>
</tr>
<tr>
<td>(n=14)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Results are expressed as mean values (± sd) where n = all patients in the group unless otherwise stated.
5.6 DISCUSSION

The entry criteria used to select patients for this study were similar to those of the previous two studies, but were broadened in an attempt to ensure that a sufficient number of patients were recruited. However, in spite of these concessions, only 25 eligible patients were recruited into this study. There were two main reasons for not meeting this target; firstly, the high intensity of work during the initial few days of a patient's stay meant that it was not possible to recruit more than two patients in the same week; and secondly, the co-investigators were undergraduate students who were on vacation during four weeks of March and April, resulting in a break in recruitment.

The aims of the study were twofold: 1) to evaluate the effectiveness of a simple nutrition education programme (NEP) on the compliance to a sip feed supplement, and to identify some of the factors associated with non-compliance and, 2) to evaluate whether the consumption of the nutritional supplement affected the nutritional intake from normal foods.

5.6.1 The effect of the Nutrition Education Programme (NEP) on patient compliance to sip feed supplements.

Compliance to the sip feed supplement was higher on the ward which received the NEP (50%) than on the ward which were not offered the NEP (36%). Although this difference was not statistically significant, this difference suggested that the NEP may have influenced one or two patients to comply to the regimen, who would not normally have done so. Without a further detailed study of a much larger group of patients this cannot be commented upon further. Compliance in this study was less than that of 61% and 62% reported in the feasibility (Chapter 3) and long term (Chapter 4) studies respectively. This could suggest that intensive patient contact could lead to a reduced rate of compliance. However, it may be that Fortisip was not as well tolerated as the supplements offered in the
previous studies. The personalities of the investigators could also influence compliance.

With regard to the NEP for nursing staff, it was the subjective viewpoint of the investigators that this did not influence patient compliance, but that the nursing staff on the ward where the NEP was instigated were generally more helpful to the researchers and genuinely interested in the project. Their greater assistance was particularly notable in the saving of patient’s meal trays, as the nurses appeared to appreciate the importance of this practice. The hypothesis behind the use of a nurse education programme was that if they were more aware of the important role that nutritional support can play and they were more involved in the study, then they would actively encourage the patients to consume the supplements. There was no evidence of this noted by the investigators, but as it was not possible to be present on the ward continually, this comment cannot be fully substantiated. As discussed in the Introduction, a good relationship and interaction between patient and Physician, and between patient and Nurse, is likely to have a beneficial role in improving compliance (Toledo et al., 1979). In addition, the frequency and duration of nurse-patient contact may be an important determinant of this relationship. The role of the nurse today is very different from the role of the nurse in the past. Today, with increasing pressures on cost and time-effectiveness, the nurse may have very little time available to spend with individual patients, other than when performing necessary functions of clinical care. A recent paper investigating the priorities assumed during times of shortages in nursing staff (Hendrickson and Doodato, 1990) reports on nurses’ perception of task priorities. In the tasks listed as inherent functions of the professional nurse, there is no mention of patient’s nutritional needs, and hence time for monitoring patient’s food intakes does not rank as a priority. Increased workload and staff shortages are common problems of a hospital ward, and nurses have little involvement at meal times. As meals tend to be served
and collected by ward clerks or auxiliary nursing staff, perhaps future nutritional education should include these groups of carers.

One of the major problems of implementing the NEP for nurses was ensuring that all the ward staff had attended the complete series of lectures. Although the ward Sister was very supportive, at times of short staffing, clinical needs prevailed and not all the nurses were able to complete the course. In these cases, written hand-outs were given to the staff which summarised the lecture, however there was no assurance that these would be read. The nurses attended these lectures voluntarily and in their own time. If more time and resources had been available, a more detailed series of lectures with an examination and a formal recognition of achievement at the end would have been incorporated into the NEP. The aim of this would have been to improve motivation and provided feedback as to the effectiveness of the NEP.

With regards to the NEP designed for the patient group, an improvement in the future design of such a study would be to include an evaluation of the patient’s nutritional knowledge prior to the introduction of the NEP, and an objective evaluation of the patient’s assimilation and understanding of the information provided. This, in conjunction with a health belief questionnaire, completed before and after the NEP, would help to clarify the effectiveness and value of the NEP taught to patients. The nutritional knowledge of 128 medical in-patients has been assessed by use of a short questionnaire (Anderson et al., 1988) which was designed to test the understanding of the principles of nutrition. The questionnaire was based on three components: familiarity with nutritional terminology, knowledge of the principles of current recommendations, and understanding of the practical applications of these recommendations. Compared with the remainder of the sample, significantly lower total scores were recorded in subjects aged 60-79 years. For the sample in general, the lowest correlation
in scores was between knowledge of theoretical principles and the understanding of practical measures required to implement these recommendations. These findings suggest that nutrition education should be directed towards food choices, rather than specific nutrients.

A nutritional knowledge questionnaire has recently been developed and validated in a group of nutrition professionals and a group of engineering students (Towler and Shepherd, 1990). Such a questionnaire could be used in future studies to evaluate the relationship between nutritional knowledge, attitude and behaviour.

If education is to revolve around advice regarding specific foods; then it is important to establish what foods are normally consumed by that person and to tailor advice to each individual accordingly. Computer analysis of weighed food intake data can identify the specific food habits of an individual in relation to frequency of consumption and portion sizes can be used to assist this task (Wise et al., 1987). When considering the diet of the elderly, in whom food choices and eating patterns are likely to be well established, educational messages are likely to be more effective if addressed in terms of changing the frequency of consumption or size of portion, rather than trying to encourage the consumption of new foods.

However, the ability to change the diet of the elderly is questionable. It has been reported that improvements in nutritional knowledge do not necessarily result in changes in food choices being made by the elderly (Davies et al., 1986). A longitudinal survey of dietary fibre intakes, before and after retirement from work, revealed that there had been a marked increase in awareness of the role of dietary fibre in preventing constipation and knowledge about dietary fibre containing foods. However, this had not altered food choices in the majority of subjects. The authors suggested that this may have been because knowledge was not related to personal
identification as constipation was not a problem to the majority of the subjects. It was therefore concluded that, in this age group, the motivation to increase dietary fibre should be linked to other areas of health concerns. In order to apply this theory to the elderly hospitalised patient, it would be necessary to perform detailed structured interviews with a similar patient population in order to identify the health concerns of this particular population. For example, in patients worried about further falls, the link between ensuring adequate energy intake could be made by explaining the advantage of a layer of fat in cushioning the impact of a fall. In someone who is apprehensive about post-operative functionality of a joint replacement, the importance of building strong muscles to hold the joint in place could be used to encourage protein intake. It is not only the content of the advice which is important, but also the manner in which it is communicated.

Although significantly higher nutritional knowledge scores have been reported in subjects who have, at some time, received dietary advice from a dietitian (Anderson et al., 1988) the traditional method of teaching used by these professionals, the structured interview, has limitations in terms of satisfaction and compliance (Davidson et al., 1987). In this review paper, it is suggested that dissatisfaction and non-compliance are related to two variables: cognitive and socio-emotional, and that a training programme on communication and counselling skills for dietetic students could help them address these problems. The short-term student evaluations of this training course were encouraging. Undoubtedly, cognitive limitations of a patient need to be considered when deciding how the information will be presented and the socio-emotional implications of the dietary advice recognised. However, since the Korner Report (1984) there is now greater pressure on all health service personnel, including dietitians, to be “efficient” and “cost-effective”. When having to work in such a climate there is always the
possibility that this may lead to the sacrifice of quality education for quantity.

5.6.2 Factors associated with poor compliance

The non-compliant patients were older than the compliant patients, similar to the findings of the long term study, although the difference in age was not significant in the current study. This was probably due to the small sample size.

Of the patients admitted for emergency surgery, 60% were compliers, almost double the compliance rate of 33% observed in the patients admitted for elective surgery. Although this difference did not reach statistical significance in this small sample size, the patient's perception of their condition and the impact that it has had on them, may have affected their response to the NEP and their attitude towards the value of supplementation. Supplementation was initiated only two days after surgery, at which time the acute effects of surgery were likely to be prominent in the patient's mind. It is possible that the patients admitted for elective surgery were feeling despondent because what was previously a chronic condition now seemed even more painful and debilitating than it was prior to hospitalisation. In contrast, the patients who were previously active and then sustained a hip fracture, may be amenable to anything that will speed recovery back to their pre-fracture state. However, this hypothesis was not reflected in the results of the Nutrition and Illness questionnaire (discussed later) and other workers have found that initial motivation and anxiety levels in hospital were not a major influence of compliance (Reid et al., 1984). In this study of factors affecting dietary compliance in coronary patients, a low level of education, low socio-economic group, lack of understanding of the illness and inadequate communication were all associated with reduced compliance. Unfortunately no assessments of socio-economic status, or level of education, were made in the current
study and so the association of these factors with compliance cannot be commented upon. A six year follow-up of the cardiac patients (Reid and Mulcathy, 1987) reported that compliance at the one year follow-up appeared to determine compliance over the longer term follow-up, especially for the "good" compliers. Clearly, to be successful in changing people's eating habits, we need to understand a lot more about the factors which influence compliance.

The mean NRS were not significantly different between the compliant and non-compliant groups, but a greater number of patients in the non-compliant group lived alone and ate alone. Poor compliance has previously been commented upon as being higher in those elderly who live alone (Cooper, 1982). Social interaction, particularly involving the family and peers, is likely to be instrumental in facilitating compliance (Glanz, 1980). In the current study, the influence of peer pressure was illustrated by patients 18 and 20, who received poor reports of the study from patient 17. The results were that patient 18 had decided that she did not like the supplement before even trying it, and patient 20 was anxious about the underlying purpose of the study and required constant reassurance that the investigators were not trying to sell her something. The influence of peer pressure was, therefore, evident. Where patients are being discharged into nursing homes or under the care of relatives, it would seem advantageous to inform them as to the important role that nutrition has to play in the post operative recovery.

The results from the "Nutrition and Illness" questionnaire indicated that there was no difference in the compliant and non-compliant groups with regard to their nutritional awareness and interest, knowledge of nutritional requirements and attempts to match these with intakes, perception of their health and life to date, or their future outlook on life. However, it should be remembered that this questionnaire has not been validated and results
should only be interpreted as a guideline. Further work in this area should involve a validated questionnaire. Discussion with researchers with the knowledge and experience in the use of this type of questionnaire, and this patient population, would be essential.

The main reasons given for the discontinuation of the supplement in the current study were the dislike of the taste or mouth feel. The supplement was often described as "too sweet" or "too sickly" and dislike attributed to dislike of milk. This preference not to consume milk was reflected in the responses to the NRQ, where 16 patients (64%) said that they consumed less than 3.5 pints of milk per week. Of these 16 patients, 10 were non-compliers and 6 were compliers. Two of the compliers admitted that they disliked the supplement and were only taking it to please the investigators.

It could be speculated that the elderly do not seem to view milk as a beverage, like the young adults do, but tend to only use it for adding to beverages such as tea and coffee. This is an interesting perception as milk and milk products have been shown to contribute significantly to the energy and protein intakes of the elderly. Seven-day weighed dietary intakes of 113 pre-retirement subjects (males approaching 65 years and females approaching 60 years) demonstrated that milk and cream provided 8% of the energy intake and 11% of the protein intake (Davies and Holdsworth, 1985). Similarly, a self completed food frequency questionnaire revealed that milk and milk products contributed 16% of total energy and 20% protein of the diet of 271 free living elderly (ages 65-75 years) in Adelaide, Australia (Baghurst and Record, 1987). For both nutrients, these sources were second only to red meat, highlighting the importance of dairy products. If milk is not regarded as a major "food" by the elderly, perhaps nutrition education should focus on encouraging the consumption of the milk-related foods which are acceptable to the group, for example milk puddings or macaroni cheese. Consideration should be given to providing supplements
in a non-milk based drink in a form which resembles a food with which they are more familiar, for example soup.

5.6.3 The use of alternative supplements to increase nutrient intake
Sip feed supplements are frequently used as a source of nutrition for cancer patients and considerable effort has been put into assessing the palatability of commercially available energy and protein supplements, and to developing recipes which incorporate the most acceptable of these into the patient's everyday diet (Parkinson et al., 1987). In this study, Polycal (Cow & Gate) was found to be the most acceptable energy supplement and Protifar (Cow & Gate) the most acceptable protein supplement when added to ten savoury and sweet recipes. The increase in nutritional value achieved with the addition of these supplements to the recipes, ranged from 16 - 151 kcal energy per portion and from 3 - 18 g protein. The mean nutritional intake of 30 patients with malignant disease on the first (unsupplemented) study day was 1515 ± 750 kcal and 57 ± 27 g protein, which increased to a mean of 1885 ± 830 kcal and 87 ± 34 g protein on the day on which the supplemented recipes were given. The mean increases of 420 kcal and 28 g protein were statistically significant (p<0.001 and p<0.000001 respectively) although the increase in energy was considered to be of little clinical value as the total intake was considerably less than the ideal energy intake of 2520-3020 kcal recommended for this group of patients. Although this method of supplementation did not attain the level necessary in a group of cancer patients, such supplements could be a valuable additional source of nutrients for patients such as the elderly surgical patient. The authors conclude that 10-40 g of Polycal (38-152 kcal) can be added to each cup of tea or coffee, depending on individual tolerance, or 30 g (114 kcal) to one portion of soup. Protifar could be used to fortify milk at the level of 50 g (183 kcal, 30 g protein) per litre then used as usual and, up to 100g per litre can be added to puddings and desserts (365 kcal
and 60 g protein). The inclusion of these additional forms of supplementation could double the level achieved in the current study with relative ease, with the additional advantage that patients could be taught to continue with this after discharge. However, as the study of Parkinson et al. (1987) involved the provision of the supplemented recipes for one day only, further studies would be required to assess the long term tolerance and compliance to supplements used in this way.

The short term and long term palatability of six commercially available oral nutritional supplements has recently been assessed in thirty cancer patients (Bolton et al., 1990). The products chosen were Build Up (Carnation Foods), Ensure (Abbott Laboratories), Fortimel and Fortical (Cow & Gate), Maxijul (Scientific Hospital Supplies) and Hycal (Beechams). This range included three of the products used in the studies presented in this thesis. Out of the 27 patients who tasted all six supplements, 13 (48%) chose Build Up, 4 (15%) chose Ensure and 0 (0%) chose Fortimel as the most acceptable product. Ten out of the 13 patients consumed Build Up for the 21 days duration of the study. These results suggest that Build Up, which contains 320 kcal and 18.2 g protein per 284 ml pack, may have been a better tolerated choice of supplement for the current study.

5.6.4 The effect of the ingestion of supplements on the nutritional intake from normal foods

When the dietary analysis was performed based on normal food intake whilst in hospital (i.e. excluding the nutritional value of the supplement), the intakes of all the nutrients assessed were higher in the compliant group than the non-compliant group. These differences were significant for the major food groups (energy, protein, fat and carbohydrate). The nutritional intakes during the period prior to hospital admission, obtained by means of a diet history, demonstrated that there were no differences in the two groups prior to admission. Therefore the higher intake in the compliant
group does not appear to be due to habitually higher food intakes in this sub population. These results could be interpreted to suggest that the provision of supplements stimulated appetite and resulted in an increased intake from normal foods. However, the use of the diet history as a method of determining nutritional intake can be criticised for the fact that the weight used to quantify portion sizes is a subjective measure, based on the individual patient's definition of small, medium or large, on which the investigator bases an objective interpretation. The inter-individual variation in portion sizes can be considerable. For example, the average weight of a portion of cornflakes of 92 adults in a Cambridgeshire village has been reported as being 35g, however, individual portion sizes varied from 14g to 85g (Bingham and Day, 1987). To confirm that the two groups had a similar intake prior to admission, it would be necessary to perform weighed food intakes in the pre-admission period. As this is not possible for the emergency admissions, a solution would be to weigh an example of the patient's food portions once they have returned to their original situation. This was not practical in the current study.

With regard to the practical difficulties of ensuring accurate data, the detailed weighing of plate food waste relied upon the trays being kept after the patients' meals. Although this generally worked well, on some occasions new staff would not be aware of the need to keep these trays and in such cases detailed 24 hour dietary intakes were performed with the aid of the hospital menu card and patients were asked to estimate proportions eaten. Ward staff and other patients assisted where the patient's memory was unclear. The estimation of plate waste was limited to approximation in terms of proportions (usually by using the descriptions of quarter, half or three-quarters). Clearly, this method reduces the accuracy of the nutrient intake assessments.
When the mean group intakes of the three hospital days were compared with the mean group intakes of the one hospital day for patients in the long term study (Chapter 4), the results were similar, with the exception of the protein intake of the non-compliers. In the current study, the mean intake of energy from normal foods (excluding the supplement) for the Compliant group, was $1609 \pm 356\text{ kcal}$, compared with $1384 \pm 227\text{ kcal}$ for the Compliant patients in the long term study. The corresponding mean daily intakes of protein were $59 \pm 11\text{ g}$ and $61.3 \pm 11.4\text{ g}$, respectively. The differences between the nutritional intakes of Compliant patients in the two studies was not significantly different. For the Non-Compliers, the mean daily energy intake was $1251 \pm 159\text{ in the current study, compared with 1062 \pm 274\text{ kcal in the long term study (not significantly different).}$ For protein, the intakes were significantly ($p<0.01$) higher in the patients current study ($75 \pm 20\text{ g}$) compared with the intakes of patient's in the in the long term study ($50.9 \pm 17.2\text{ g}$). No obvious explanation can be found for this difference. Neither the compliant nor the non-compliant sub-groups of the current study met their daily RNI for energy [(1900 kcal for ages 65-74 and 1810 kcal for aged 75+ (DHSS, 1991)]. Daily protein intakes, however, were met [$46.5\text{ g}$ (DHSS, 1991)] from normal foods alone. It should be remembered that these recommendations do not include the additional requirements imposed as a result of surgery and therefore intakes can be considered inadequate, particularly with regard to energy intake. Interestingly, mean daily energy intakes of pre-retirement women, approaching the age of 60 years, have been assessed by seven day dietary weighing and reported to be $1730 \pm 400\text{ kcal}$ (Davies and Holdsworth, 1985). Considering that 60% of these women classified themselves as "moderately" active and a further 33% considered themselves "very" or "extremely" active, these results could suggest that the current RNI's are too high. Forty-nine percent of these women reported altering their food intake in order to control body weight, and unfortunately, the results were
not reported separately for the group who were not trying to control their body weight.

The nutritional value of the supplements consumed by the majority of the patients was 600 kcal and 20 g protein (equivalent to 2 cartons of Fortisip), but actual intake ranged from 1-3 cartons per day. The volume consumed was observed to increase over the period of study, suggesting that if patients were asked to start the supplement several days later, they may have been able to consume a greater amount. Compliance may also have been improved. The mean daily nutrient intake of the compliant group, when the nutritional value of the supplements were included, was 2095 ± 284 kcal energy and 73 ± 10 g protein, exceeding the RNI’s for a healthy free-living elderly population. This was unlikely to meet the additional energy needs of post-surgical patients (as discussed in Chapter 1.1).

5.6.5 **Outcome of compliant and non-compliant patients**

According to the results of the anthropometric assessments and the duration of stay in hospital, the supplements did not appear to convey any benefit in terms of body composition or speed at which recovery is achieved. Although significant differences in anthropometric variables had been noted in the feasibility study from admission to discharge (Chapter 3), they were not observed in the long term study. In the long term study (Chapter 4), the most notable differences were not revealed until the convalescent period following discharge from the acute hospital. It is therefore, not surprising that no differences were reported in the current study.

As discussed previously, duration of stay in the acute hospital is determined by many additional factors other than the patient’s stage of recovery and it is not surprising that there was no difference between the groups.
5.7 CONCLUSION

The Nutrition Education Programme described in this study did not appear to influence patient compliance to the supplement. However, the nutritional education and involvement of the nursing staff did seem to improve the general running of the study and was considered beneficial. Inclusion of those staff who are involved in food selection and service (the ward orderlies and ward clerks) is thought to be important in the design of future studies. The content and structure of the NEP may not have optimised the possible benefits of nutrition education. In view of the observation that there was great interest but little commitment from the nurses, a more formal approach may be advantageous, with an incentive to assimilate the information being incorporated. The patient NEP may have influenced a small number of individuals to comply to the regimen, but the perceived relevance, and the understanding of the information provided, was not assessed.

The principal reasons for non-compliance centred around the patients’ perceived dislike of milky products. If closer attention could be given to patients’ individual likes and dislikes, then it may be possible to improve compliance by incorporating supplement products into the recipes of foods commonly eaten by the elderly.

The dietary data indicated that consumption of the supplements may stimulate appetite and increase the consumption of normal foods. However, the results could also be interpreted to mean that the patients who have a naturally higher food intake are the ones who will be more inclined to consume additional "food" in the form of the supplements. In order to clarify which of these interpretations is correct, it would be necessary to perform detailed pre-hospital dietary assessments of the patients and continue to monitor dietary intake during hospitalisation. It would also be valuable to extend these detailed dietary evaluations into the post-discharge
period. In order to obtain a detailed and accurate representation of dietary intake and meal patterns in the elderly, the use of four simultaneous techniques has been recommended (Holdsworth et al., 1984). The techniques used in this four year longitudinal study of the elderly, before and after retirement, were: a week’s weighed dietary record; a recall of customary food and beverages consumed throughout a typical day; a questionnaire incorporating questions relating to foods and drinks; and frequency of consumption lists for specific foods. Such a comprehensive approach was costly, particularly in terms of staff resources, but such cost should be balanced against the validity and accuracy of the data obtained.
Chapter 6

General Discussion
Chapter 6
GENERAL DISCUSSION

6.1 GENERAL DISCUSSION

The elderly are becoming an increasingly large proportion of both the population in general, and the population in our hospitals. Malnutrition, whether clinical or subclinical in nature, is becoming acknowledged as a problem in elderly patients living in the community, in institutions and in hospitals (Lehmann, 1989). The degree of undernutrition present on admission to hospital may be further exacerbated during the hospital stay, particularly in surgical patients where the hyper-metabolic effects imposed by trauma or surgery are frequently coupled with low food intakes. Meeting nutritional requirements during the immediate post operative period is increasingly being accepted as an important aspect of clinical management.

Supplemental nutrition, in the form of sip feed drinks, can offer a relatively simple and inexpensive method of increasing the nutritional intake of vulnerable patients. In order for this support to be targeted effectively, it is first necessary to identify individuals who are likely to be nutritionally at risk. The method employed to identify "at risk" individuals in the three studies presented in the preceding chapters was a simple check-list of factors which have been associated with poor nutritional status. A long term follow up of the outcomes of the "High Risk" patients compared with the outcomes of the "Low Risk" patients, supported the use of this assessment tool (Lumbers, 1993).

The elderly orthopaedic patient was chosen as the subject for study in the work presented in this thesis. The reason for the choice of this group of patients was that they represent a large proportion of the elderly hospital population. By restricting inclusion to those patients admitted to hospital for emergency surgery for repair of a fractured hip, or elective surgery for a hip joint replacement, a relatively homogenous population was provided for study. Nutritional assessment studies of elderly orthopaedic patients
have reported that approximately 50% of this group have one or more abnormal findings, indicative of protein calorie malnutrition, on admission to hospital (Bistrian et al., 1974; Hill et al., 1977; Dreblow et al., 1981). The elderly hip fracture patient often has a very low body weight with low body protein and fat stores. The lack of body fat means that there is little cushioning of the impact of a fall, hence a fracture is likely to result. A low muscle mass has also been regarded as a substantial contributor to fractures in the elderly (Waller, 1978). These observations high-light the importance of ensuring that no further deterioration occurs in nutritional status during the hospital stay, if the impact of further falls is to be minimised. Patients admitted to hospital for hip replacement surgery appeared to be less nutritionally compromised (Chapters 3 and 4), but the preservation of good nutritional status is important if recovery is to be optimised.

The provision of nutritional sip feed supplements to the patients in the studies presented here was associated with both short term and long term benefits. The supplements were provided during the early post operative and convalescence period, the period when morbidity and mortality are known to be highest. Benefits were observed in terms of nutritional variables and clinical outcome parameters. The groups who were not offered the supplements demonstrated significant decreases in nutritional indices, particularly those indicative of protein status in the early post operative period. In contrast, the group receiving the supplements demonstrated either no significant (Chapter 3), or less severe (Chapter 4), declines in the early post operative weeks. In the long term evaluation study (Chapter 4) the group not receiving the supplements did not show a recovery in these nutritional parameters until the assessment made at six months after discharge from the acute hospital. In contrast, the groups who were offered the supplements demonstrated either no such decline, or a faster recovery to the baseline values. The longer term study, however,
could be criticized because of the difference in body weight which was apparent between the two groups on admission to hospital. This was considered to be a result of studying a small group of patients, although similar differences were reported in the two similar groups studied by Delmi et al (1990). The longer term study (Chapter 4) also showed large differences in the total length of time which the patients were required to spend in hospital (acute and convalescence period combined). The results indicated that the patients receiving the supplements were able to return to a more independent way of life at an earlier stage than those not offered the supplements. Differences in six month mortality rates and infection rates were also observed, being more favourable in the group who were consuming the supplements. Although these differences were apparent at the final assessment (six months after discharge from the acute hospital) this period of evaluation could be considered relatively short when considering the total life span of these patients. A longer period of follow up would be required to assess whether this medium term benefit is continued into the future.

The potential benefits of supplementation will only be attained if the supplements are actually consumed. The three studies presented here (each studying a similar patient population) have all identified poor compliance to be a major problem, with only 50-65% of the patients taking the supplements and many of those in quantities less than prescribed. This problem was first highlighted in the feasibility study (Chapter 3) and led to attempts to improve this situation by changes in the design of the longer term study (Chapter 4). Despite offering a variety of supplements, compliance was not improved. This suggested that flavour and mouth feel were not important determinants of compliance, but the patient's attitude towards the value of the supplements and the role of nutrition in recovery was considered a possible influential factor. This perception resulted in the design of the third study, in which the effect of a nutrition education
programme, on compliance, was evaluated (Chapter 5). The results suggested that the provision of information regarding the role of nutrition in recovery did not improve the rate of compliance. However, the study could be criticised for the lack of evaluation of knowledge and understanding before and after the implementation of the programme. There was some subjective evidence to suggest that the nurses on the ward which had received the nutrition education programme, were more motivated to assist in the study and more aware of the importance of nutrition in the role of recovery. The relationship that exists between nurse and patient is one of closeness and respect. One of the important roles of the nurse is to communicate information to the patient. Nutritional information may be best received by the patient in a very practical way. The nurse could offer a link between the professional dietitian and the patient. The hospital dietitian has a vast knowledge, but does not have the time to assess and monitor the nutritional status of all patients admitted to hospital. If the dietitian became more involved in the nutritional education of other health professionals, such as the ward staff, a much larger group of patients would derive potential benefit. This role would not only serve to make more efficient use of the dietitian’s time and leave her/him more time to dedicate to specialist cases, it would also increase the professional profile of the dietitian. This would not have to be limited to the hospital dietitian. In the community, dietitians have been involved in the training of, and liaison with, district nurses and health visitors for several years. With the current emphasis on primary care in the community, the practice nurse is becoming increasingly involved in primary patient care. If these nurses could be trained to recognise signs of poor nutrition and to understand the role of nutrition during recovery, they in turn, could educate the general practitioner with a view to the prescription of energy and protein supplements. Already some general practice surgeries are considering the possibility of the giving the practice nurse the authority to write limited prescriptions. If this is to be the way forward, the
practice nurse is likely is to become an influential member of the primary care team. This sentiment is echoed in the recently published *Kings Fund Centre Report* (1992). One of the aims and recommendations of this report was to "improve awareness and understanding by doctors and nurses of under-nutrition and its consequences". This report also recognised that nutritional support should be prescribed by the general practitioner and that the current regulations need reviewing and amending in order to allow this to become routine practice.

No differences were observed in the responses to the "Nutrition and Illness" questionnaires, which were designed to evaluate the attitude and motivation towards the value of the supplements, although this questionnaire is accepted as being a crude, non-validated method of assessment.

The nutritional medium used as a vector for increasing nutrient intake was a milky based drink, which may be an inappropriate choice for this group of patients. From the 24 hour dietary recall data, it was revealed that milk was not a beverage which was consumed by this patient population and may, therefore, not be the optimum medium for increasing nutrient intake in the elderly. It could be speculated that a nutritional supplement is more likely to be consumed if it resembles a food which is familiar and consumed regularly. As the elderly are becoming an increasingly large proportion of our hospitalised population, and are a potentially nutritionally vulnerable group, it would be worth investing more time and effort into researching which foods would be acceptable as mediums for supplementation with additional nutrients. To ensure regular intakes, these should be foods which are not only acceptable, but are consumed frequently. Possibilities could include products which can be incorporated into usual foods to increase nutrient density, or supplemented milk puddings which could be
provided in "ready to eat" packages. Research into acceptable presentation would also be important.

Clearly further investigation into factors which motivate patients to comply is warranted. The outcomes of the patients who were allocated the supplements but did not comply to the regimen (Chapter 4) suggested that the patients who do not ingest the supplement voluntarily may be the most vulnerable. A more invasive form of nutritional support, such as naso-gastric feeding, should be considered in such patients. However, in this potentially large number of patients, naso-gastric feeding would prove extremely costly and would be anticipated to be poorly tolerated by the patients (Bastow et al., 1983a).

The results of these studies (Chapter 4 and Chapter 5) indicated that nutrient intake from normal foods was not adversely affected at the level of supplementation attained. However, the additional nutrients provided were not sufficient to result in a clinically significant net gain in body weight. Some patients still had very low body weights at the end of the period of supplementation and, if a suitable medium was to be found, attempts should be made to increase the level of energy intake further. Care must be taken to ensure that this is efficiently utilised by the body, and that any excess of energy is not converted into fat stores, whilst body protein stores are utilised for energy. Clearly there is some sort of adaptation to metabolic fuel utilisation in trauma which makes the anabolism of lean body mass difficult.

The results of the present study have encouraging and discouraging aspects. On the plus side there is clear cut evidence that patients who adhere to supplemental nutrition, throughout their period of convalescence, have improved clinical outcome in terms of:
1) Maintenance of pre-operative nutritional status.
2) Faster return to pre-operative serum albumin.
3) Shorter periods of hospital stay.
4) Reduced complication and mortality rates.

However 40% of patients fail to adhere to the supplement, including some of the most vulnerable. These results suggest that more aggressive approaches to nutritional support are justified. This could include the use of pharmacological support in an attempt to aid the utilisation of supplemental nutrients. To discuss the potential benefits of including pharmacological support, the metabolic response to trauma will be summarised and the use of anabolic growth factors discussed. This topic will be discussed in terms of general surgical and traumatised patients, with the potential benefit to the elderly orthopaedic patient in mind.

It was the pioneering work of Cuthbertson, starting in the 1930's, which has formed the basis of our present understanding of the metabolic response to injury. It was he who coined the now well used terminologies of, the "ebb phase", to describe the initial general depression in metabolic activity, and the "flow phase" to describe the later hyper-metabolic response as the host responds to compensate for the injury. Trauma is followed by endocrine and metabolic changes initiated both at the central nervous system (hypothalamus) and at the periphery (sensors detecting changes in blood volume or pressure). The aims of these changes are twofold: to maintain blood volume and circulatory homeostasis, and to provide nutrients and oxygen to the cells of the vital organs.

During the ebb phase, cardiac output, oxygen consumption and body temperature are all decreased. There is an increase in sympathoadrenal activity resulting in raised blood levels of catecholamines. The elevation of catecholamines results in reduced levels of circulating insulin and
accelerated lipolysis. In turn, this raises the concentration of free fatty acids which are then used as a source of energy. Lactate and pyruvate levels increase, reflecting anaerobic glycolysis, inadequate tissue perfusion and metabolic acidosis. As a consequence of inadequate hepatic perfusion, gluconeogenesis may be impaired and the glycogen stores in the liver and muscle may be gradually depleted. Although glycogenolysis is accelerated, glucose oxidation is diminished.

When patient responses and resuscitative measures are sufficient to restore deficits in circulating volume and improve tissue oxygenation, metabolic activity gradually increases and rises above basal levels. The patient is now moving into the flow phase, when cardiac output, metabolic rate and body temperature all increase. Ureagenesis is accelerated and there is an increased excretion of urinary nitrogen. Blood glucose may be elevated but the degree of hyperglycaemia is not proportional to hepatic glucose production, which is also increased. Circulating insulin levels are normal or elevated, but a degree of insulin resistance develops. Lipolysis is accelerated and fat serves as the main fuel for oxidation. The basal concentration of circulating growth hormone is also elevated. This is likely to contribute to the lipolysis, glucose intolerance and exaggerated insulin response which occurs in catabolic patients.

If the injury is extensive, or homeostatic responses and resuscitation are ineffective, the ebb phase persists, characterised by profound lactic acidosis. The duration of the ebb phase seems to be an important determinant of clinical outcome. Increased mortality is observed in trauma patients who have persistently low oxygen consumption as compared with those who have normal or increased metabolic rates. The duration and magnitude of the flow phase vary with the severity of the injury and gradually subside as wound healing and convalescence prevail.
An uncomplicated, elective surgical operation will impose minimal metabolic stress on a previously healthy individual and will elicit only a mild and short-lived response. In such cases, the loss of body protein may be only slightly more than would be observed in a normal individual who has undergone a similar period of fasting. In contrast, a major thermal injury complicated by sepsis will cause a marked and prolonged response, with severe consequences on the protein and energy stores of the body. The body composition of the patient prior to the trauma and the nutritional intake during the ebb and flow phase are important determinants in the ability of the patient to cope with these metabolic changes.

Some mediators, principally the interleukins originating from the macrophages and lymphocytes at the site of tissue damage, have been shown to influence intermediary metabolism, particularly of proteins (muscle proteolysis and hepatic plasma clearance of amino acids). The role of these mediators is not fully understood and will not be discussed further.

In summary, trauma patients have an increased oxygen consumption; glucose turnover and lipolysis is increased but the ability to oxidise glucose is reduced; and there is a net protein degradation resulting from an increased protein catabolism partially counteracted by a minor increase in protein synthesis (Sitges-Serra, 1991). One feature of the accelerated catabolism is the mobilisation of proteins from skeletal muscle. Protein malnutrition may delay wound healing and reduce resistance to infection, thereby jeopardising recovery. The changes in protein metabolism observed in post surgical patients and the critically ill are associated with an acquired growth hormone (GH) resistant state. In view of this, recent attention has been focused on the role of the GH / IGF-1 (insulin like growth factor 1) axis. GH is released in a pulsatile nature from the anterior pituitary gland and stimulates the synthesis of IGF-1 in various tissues, the liver being the source of the majority of circulating IGF-1. IGF-
1 is thought to mediate many of the anabolic actions of GH and it is carried in the circulation by a number of binding proteins. These binding proteins modulate the bio-availability of IGF-1 and its presentation to IGF-1 receptors in the tissues. To date, six of these binding proteins have been characterised, of which detailed physiological actions of three are known (IGFBP-1 to IGFBP-3). IGFBP-3 is the most abundant binding protein with a long half-life and, provides an intravascular store of IGF-1. IGFBP-1 shows an inverse relationship to insulin and appears to be acutely regulated by insulin and nutritional status. In bio-assays, IGFBP-1 appears to inhibit the action of IGF-1. IGFBP-2 is a carrier protein whose levels rise at times of low levels of IGFBP-3. In the normal physiological state, GH has both direct and indirect actions. As described above, the growth promoting anabolic actions of GH are "indirect" and are largely mediated through generation of IGF-1. The "direct" actions of GH are primarily antagonistic to insulin, although there are acute insulin-like effects which are of uncertain physiological significance. It is these direct actions which are important in the metabolic response to trauma. The role of GH and IGF-1 in the post surgical or critically ill patient will now be discussed further.

It was over 20 years ago that a case history was first published which correlated low serum growth hormone levels (in response to provocation stimuli) with delayed fracture union in a young, otherwise healthy, adult male (Misol, 1971). It was almost another 15 years before GH could be genetically engineered and produced on sufficient scale for it to become commercially available. This technological development led to further investigations as to the role of GH in wound healing and critically ill patients. The beneficial effects of GH administration on wound healing and a reduced length of stay in hospital have been reported in severely burned children when given in conjunction with adequate enteral nutrition to meet calculated calorie requirements (Herndon et al., 1990). Work continues in this therapeutic area (Gilpin and Herndon, 1993).
Attention has also been focused on the use of GH after major surgery or trauma. The metabolic response to a major elective intra-abdominal operation is characterised by weight loss and negative nitrogen balance. The administration of low dose GH and hypocaloric nutrition has been investigated in patients after elective gastrectomy or colonectomy (1990 Jiang et al., 1989). Results revealed that giving daily injections of GH during the first post operative week significantly reduced weight loss and nitrogen loss. Kinetic studies demonstrated the anabolic effects of GH were associated with increased protein synthesis. Analysis of hand grip force showed a 10% loss of grip strength in the control subjects, whereas the patients receiving GH maintained their grip strength throughout the post operative period.

Further evidence to support the administration of GH, in combination with nutritional support, comes from the work of Ziegler et al. (1990) where eleven patients with severe burns or vehicular trauma were given daily injections of GH for one to six consecutive weeks. During the first two weeks of study, nitrogen excretion decreased (p<0.002) as did potassium and phosphorus excretion. The protein conserving effects of GH were sustained during the following weeks of treatment. Calculated nutrient requirements were administered either by parenteral or enteral tube feeding, as appropriate, and additional oral food intake was permitted. The administration of GH enhanced the efficiency of administered protein and facilitated nitrogen retention. Clearly further work is required in a larger group of patients to determine whether the use of this anabolic hormone reduces hospitalisation time and improves other clinical outcome parameters, but results are encouraging. A pilot study is currently being undertaken in Australia to evaluate the effects of GH administration on muscle preservation following trochanteric fracture of the femur (Gillespie, unpublished). The results of this study may have widespread implications.
with regard to the clinical management of hip fracture, and hip replacement, patients.

The mechanism by which the administration of GH promotes protein synthesis would seem likely to be mediated by the anabolic action of IGF-1. The relationship between GH and IGF-1 in critically ill patients has recently been investigated (Ross et al., 1991). An understanding of the GH-IGF axis is essential in order to develop optimal new therapies aimed at improving the nutritional state of these patients. Six critically ill patients admitted to the intensive therapy unit of the Royal Sussex County Hospital who required ventilation and parenteral nutrition were studied. These patients were matched with healthy adults. To highlight the main findings, the patients demonstrated elevated baseline GH levels compared with controls, both when fasted and during parenteral feeding. The GH secretion in the controls was oscillatory in nature (normal physiological response) whether fasted or fed, but this activity was attenuated in these patients. Despite the elevated GH levels, the patients had low serum IGF-1 concentrations compared with controls, in both the fasted and fed states. In conclusion, these observations suggest that in critically ill patients there is a "GH-resistant state" both prior to and after parenteral feeding. There appears to be an adaptive change from the indirect effects of GH (anabolism and protein synthesis mediated by IGF-1) to the direct effects (lipolysis and insulin antagonism). These physiological adaptations may no longer be an advantage to the patient with modern methods of intensive care and nutritional support, and therapy with GH or IGF-1 may benefit critically ill patients. Whether the same adaptations are apparent in the less traumatised patient undergoing hip surgery requires further investigation.

At the present time, IGF-1 is not available commercially and future clinical studies would initially have to be limited to the evaluation of the effect of GH. From the current literature, it would seem the most appropriate time
to incorporate a short period of GH administration into the clinical management of hip surgery patients, would be during the acute catabolic phase, a week or two following surgery. Determination of serum concentrations of IGF-1 and its associated binding proteins would provide valuable information regarding the underlying metabolic mechanisms. As growth hormone is a relatively expensive drug, the cost of this treatment must be balanced against potential costs saved by a reduction of stay in hospital, lower infection and readmission rates and improved patient care. The most appropriate dose of GH to use in these patients has yet to be clearly defined, but recent studies have suggested a dose in the region of 0.3 IU/kg/day. At current market prices, this would cost approximately £122 per day for a 50-55 kg patient. This is similar to the cost of providing parenteral nutrition, the cost of which has been clearly justified when offset against the costs of complications and prolonged hospital stay (Reilly et al., 1988). Further work in this area should incorporate an aspect of cost-effectiveness or cost-benefit analysis. In a review of the methods of assessing cost analysis studies of total parenteral nutrition, Eisenberg et al have proposed an outline of study design for economic assessment which would provide a useful guide to the planning of such a study (Eisenberg et al., 1988).

The importance of measuring the outcome of any dietary intervention, including the provision of supplemental nutrition, has reached a new dimension since the Government’s white paper (NHS, 1989) proposed that a comprehensive system of medical audit should be developed for primary health care, hospital and community services. The British Government defines medical audit as the systematic, critical analysis of the quality of medical care, including the procedures used for diagnosis and treatment, the use of resources, and the resulting outcome and quality of life of the patient. Measuring outcome of nutritional intervention is not always easy. Clinical outcome is important when considering implications to the
resources of the NHS, but it could be argued that of equal importance is the benefit perceived by the patients themselves, with respect to the effect that a treatment has on their quality of life. It may be assumed that outcome will be directly determined by the quality of medical and nutritional care. However, other factors such as poor compliance, lack of motivation, poor social conditions, inadequate cooking facilities, lack of finances, and lack of extended family support will all influence outcome (MacDonald, 1990). These factors will all affect the patient’s perceived quality of life, but the provision of nutritional support may affect perceived quality of life in other ways. In the studies reported in this thesis (Chapters 3, 4 and 5), no attempt was made to evaluate whether the provision of sip feed supplements affected the patient’s quality of life. However, there is an increasing awareness of the importance of using quality of life as part of the assessments to measure the impact of illness, disease, and their treatment, and for deciding priorities when allocating resources. The impact of total hip replacement on quality of life has been assessed retrospectively, in patients who have suffered from osteoarthritis of the hip, using a modified version of the Arthritis Impact Measurement Scale (Selman, 1989). More recently a prospective intervention study was undertaken in a similar group of patients, again using the Arthritis Impact Measurement Scale and also the McMaster Health Index questionnaire and a Schedule for the Evaluation of Individual Quality of Life (SEIQoL), (O’Boyle et al., 1992). The SEIQoL method was devised from the technique known as judgement analysis to measure patients’ level of functioning in five self-nominated facets of life and the relative weight or importance attached to these areas. These facets are derived for each individual patient from structured interviews and are able to quantify the impact of the disease or treatment on aspects of life which are important to that individual patient. The author of this thesis is not aware of a SEIQoL which has been developed for use in patients with hip fractures, although presumably the same principles would apply. One questionnaire which may be considered appropriate for
use in both hip fracture and hip replacement patients would be the Nottingham Health Profile (Hunt et al., 1985). Although designed as a general health questionnaire, use in this group of patients would be regarded as appropriate (personal communication). There are many measures of general health and well-being of the patient which have been designed for use in orthopaedic patients (Pynsent et al., 1993). Before selecting one (or more), it would be necessary to test the questionnaire in this group of patients to ensure that it was valid, accurate and sensitive to change.

6.2 RECOMMENDATIONS FOR FUTURE WORK

The results of the studies presented in the preceding chapters have indicated that the provision of nutritional supplements during the first few weeks following surgery can convey short term benefits, in terms of nutritional status; and medium term benefits, in terms of reduced infections and mortality. Within the framework of these studies, it was not possible to determine whether any lasting long term benefit was conferred. In order to assess this, it is suggested that a large cohort of patients be studied for a period of at least 5 years. This would enable not only long term effects on body weight and composition to be reported, but also collation of data regarding frequency of repeated falls, hospital readmission rates and mortality rates. Before implementing such a study, the problem of poor compliance would clearly need to be addressed. Alternative methods of providing the target level of nutritional support must be considered. Ideally the study would have two treatment groups; 1) nutritional supplementation and 2) nutritional supplementation plus a short period of growth hormone treatment in the early post operative period. A third group could serve as a "control" with patients receiving routine clinical treatment. The possibility (and ethics) of a placebo controlled group should also be considered. In view of the future high cost implications, an economic
evaluation should be incorporated into the design. The outcome criteria should not only be restricted to objective clinical measures, but should also include a subjective self-assessment of the patient's quality of life. For logistical and economic reasons, before embarking on such a long term project, a feasibility study should be performed in order to refine procedures and outcome variables.

Although the above recommendations apply to the elderly orthopaedic surgical patient, on a more general note, the role of the dietitian in training and education of nursing staff and other health care professions to recognise nutritionally vulnerable patients should be more fully evaluated.


Bisson J. (1990). The effect of nutrition education on compliance of patients to sip-feed supplements. *University of Surrey, final year project.*


AUTHOR'S PUBLICATIONS


LDREFS/29 March 1994
Appendix

I
### Appendix I

#### Table A1.1

The elderly male population in the UK

<table>
<thead>
<tr>
<th>Year</th>
<th>Total population</th>
<th>60-64 years</th>
<th>65-74 years</th>
<th>75-84 years</th>
<th>85+ years</th>
</tr>
</thead>
<tbody>
<tr>
<td>1961</td>
<td>27,279</td>
<td>1,539</td>
<td>2,372</td>
<td>1,210</td>
<td>241</td>
</tr>
<tr>
<td>1971</td>
<td>28,761</td>
<td>1,715</td>
<td>2,765</td>
<td>1,443</td>
<td>359</td>
</tr>
<tr>
<td>1981</td>
<td>28,943</td>
<td>1,559</td>
<td>2,931</td>
<td>1,755</td>
<td>461</td>
</tr>
<tr>
<td>1986</td>
<td>29,116</td>
<td>1,598</td>
<td>2,805</td>
<td>1,908</td>
<td>543</td>
</tr>
<tr>
<td>1990</td>
<td>29,398</td>
<td>1,502</td>
<td>2,767</td>
<td>1,975</td>
<td>647</td>
</tr>
</tbody>
</table>


#### Table A1.2

The elderly male population in the UK

<table>
<thead>
<tr>
<th>Year</th>
<th>Total population</th>
<th>60-64 years</th>
<th>65-74 years</th>
<th>75-84 years</th>
<th>85+ years</th>
</tr>
</thead>
<tbody>
<tr>
<td>1961</td>
<td>25,528</td>
<td>1,249</td>
<td>1,605</td>
<td>675</td>
<td>105</td>
</tr>
<tr>
<td>1971</td>
<td>27,167</td>
<td>1,507</td>
<td>1,999</td>
<td>716</td>
<td>126</td>
</tr>
<tr>
<td>1981</td>
<td>27,409</td>
<td>1,376</td>
<td>2,264</td>
<td>921</td>
<td>141</td>
</tr>
<tr>
<td>1986</td>
<td>27,647</td>
<td>1,485</td>
<td>2,201</td>
<td>1,060</td>
<td>166</td>
</tr>
<tr>
<td>1990</td>
<td>28,013</td>
<td>1,394</td>
<td>2,241</td>
<td>1,140</td>
<td>219</td>
</tr>
</tbody>
</table>

Appendix II
Appendix II
Nutrition Risk Questionnaire

NUTRITION RISK ASSESSMENT  SCORE:

Patient Name:  Date of Admission:
Age:  Date of Interview:

Place a tick against any statement which applies to the patient:

The Patient:

☐ Lives alone
☐ Lives alone and has regular visitors less than twice per week
☐ Lives in a residential home
☐ Is over 60
☐ Is over 80
☐ Is over 90
☐ Has experienced a major life crisis in the last 12 months
  (e.g. moving house/divorce/separation/bereavement)
☐ Has no regular hobbies or pastimes
☐ Is unable to walk more than 400 yds unaided
☐ Leaves the house less than twice a week

The Patient Has:

☐ Falling vision (other than normal use of spectacles)
☐ Cancer
☐ Diabetes Mellitus
☐ Gastrointestinal disease
☐ Bronchitic disease
☐ Physical disability which impairs dexterity/mobility
☐ Mental disability which prevents normal communication
☐ Osteoarthritis
☐ Undergone surgery in the past 6 months
☐ Been bedridden for more than 3 months
☐ Been admitted for:
  Surgery
  Radiotherapy
  Chemotherapy
☐ A history of frequent falls
☐ Poor dentition, ill fitting dentures
The Patient:

- Could be described as thin
- Could be described as very thin
- Has a small appetite
- Has lost more than 7 lbs (without dieting) in the past 2 months
- Avoids a particular food/group of foods due to intolerance
- Has restricted their diet in the past 6 months in order to lose weight
- Has impaired sense of taste/smell
- Has frequent episodes of:
  - nausea
  - vomiting
  - diarrhoea
  - constipation
- Eats alone more than 4 days a week
- Eats less than 5 cooked meals per week
- Regularly skips meals, e.g. breakfast
- Never eats the following:
  - red meat
  - white meat or fish
  - milk or dairy products
  - eggs
- Drinks less than 3½ pts. milk a week
- Eats less than 3 servings of fruit/fruit juice a week or less than 3 servings of vegetables a week
- Uses laxatives more than twice a week
- Expresses a lack of interest in food and food preparation
- Is totally dependent on others for meal provision
- Has expressed episodes of apathy or depression

For Patients Living in their Own Homes/Independently

The Patient:

- Requires help with shopping
- Requires assistance with preparation/cooking of food
- Requires, but does not receive sufficient assistance with above activities
- Does not have easy access to food stores/supermarkets
- Relies on public transport/walking for shopping
- Relies on others to get shopping
Appendix II
Northwick Park Mental Function

MEMORY AND AWARENESS TEST

1. What is your name?
2. How old are you?
3. What year is it?
4. What day is it?
5. What is the name of this hospital?
6. What is the name of this ward?
   (Inform if not known)
7. Repeat these numbers, but in numerical order - 6, 2, 7, 3
8. I'm going to tell you an address and I want you to remember it: 74 Columbia Road
9. What year did WW2 start?
10. What year did WW2 end?
11. Who was the prime minister at the end of the war?
12. Who was the prime minister at the beginning of the war?
13. Who is the prime minister now?
14. What is the name of the Queen?
15. What is the name of her eldest son?
16. Where is Chernobyl?
17. What happened there recently?
18. Tell me the name of the hospital again.
19. Tell me the name of the ward again.
20. What was the address I told you?
21. What is my name?

SCORE:
CLIFTON ASSESSMENT PROCEDURES FOR THE ELDERLY (CAPE)

Cognitive Assessment Scale

Name: .............................................

Current address/placement: .............................................

Date of birth: ............................................. Occupation: .............................................

Information/Orientation

Name: ............................................. Hospital/Address: ............................................. Colour of British Flag: .............................................

Age: ............................................. City: ............................................. Day: .............................................

D.o.B. ............................................. P.M.: ............................................. Month: .............................................

Ward/Place: ............................................. U.S. President: ............................................. Year: .............................................

I/O Score: .............................................

Mental Ability

Count 1-20

Time: Errors: 3 2 1 0
≤10 secs - no errors ≤30 secs - no errors ≤30 secs - 1 error
≤30 secs - no errors

Alphabet

Time: Errors: 3 2 1 0
≤10 secs - no errors ≤30 secs - no errors ≤30 secs - 1 error

Reading: (See overleaf)

Write name:

Correct and legible: 2 1 0
Can write but not correctly
Not able to

Decoding: 3 2 1 0

MAb Score: .............................................
Appendix II
Reading List for CAPE CAS

free
saying
plain
picture
hostage
twisted
sponge
shoulder
knowing
physical
decent
comprehend
atmosphere
precocious
Appendix II
Instructions and scoring for CAS

Directions and scoring criteria are as follows:

Information/Orientation
Each correct response is given one point.
1. What is your name/full name?
2. How old are you?
3. What is your date of birth?
4. What is this place/Where are you now?
5. What is the name of this hospital/What is the address of this place?
6. What is the name of this town/city?
7. Who is the Prime Minister?
8. Who is the President of the United States of America?
9. What are the colours of the British flag/Union Jack?
10. What day is it?
11. What month is it?
12. What year is it?

Mental Ability
Will you count up from 1 to 20 for me — as quickly as you can?
Now, can you say the alphabet — again as quickly as you can?
Will you read these words out loud for me?
Will/can you write your name here for me? Please write it clearly.

First name and surname are both required.
Present age in years or predicted age next birthday, e.g. 79 next August.
The date, month and year must all be correctly given.
The name of the hospital ward or recognition that it is a hospital ward is required for hospital patients; recognition that they are in their own home, social services accommodation or whatever for non-hospital subjects.

Name of hospital is required, street address of the home, or, if in their own home, number and street name, as appropriate.
The correct name of the town or city in which they are currently located.
Surname of the current P.M. is sufficient.
Surname of the current president.

Red, white and blue.
The day of the week, not date, is required.
(This can be explained once if the date is given).
Current month.
Current year.

The prompt 1, 2, 3 may be given.
Time in seconds and number of errors are recorded.
The prompt a, b, c may be given.
Again the time taken and number of errors are recorded.
A second test form is usually offered to the subject so that the examiner can mark the correctly read words on the test form being used.
The name must include either first name and surname, correct and legible, or title (Mr, Miss, Dr) and surname. If there are errors, or the name is not clear, score 1, but if the person is unable to write out his name correctly or it is illegible, score 0.
Appendix III

Table A3.1
ENSURE (Abbott Laboratories)

Nutritional composition per can (250 mls)

<table>
<thead>
<tr>
<th>NUTRIENT</th>
<th>AMOUNT per can</th>
<th>NUTRIENT</th>
<th>AMOUNT per can</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein</td>
<td>8.8 g</td>
<td>Water</td>
<td>200 g</td>
</tr>
<tr>
<td>Carbohydrate</td>
<td>34.3 g</td>
<td>Ash</td>
<td>1.4</td>
</tr>
<tr>
<td>Fat</td>
<td>8.8 g</td>
<td>Energy</td>
<td>250</td>
</tr>
<tr>
<td>Vit A</td>
<td>625 IU</td>
<td>Vit D</td>
<td>50 IU</td>
</tr>
<tr>
<td>Vit E</td>
<td>5.63 IU</td>
<td>Vit K₁</td>
<td>9 µg</td>
</tr>
<tr>
<td>Vit C</td>
<td>37.5 mg</td>
<td>Folic acid</td>
<td>50 µg</td>
</tr>
<tr>
<td>Thiamine (Vit B₁)</td>
<td>0.38 µg</td>
<td>Riboflavin (B₂)</td>
<td>0.43 mg</td>
</tr>
<tr>
<td>Vit B₆</td>
<td>0.50 mg</td>
<td>Vit B₁₂</td>
<td>1.5 µg</td>
</tr>
<tr>
<td>Niacin</td>
<td>5.0 mg</td>
<td>Choline</td>
<td>75 mg</td>
</tr>
<tr>
<td>Biotin</td>
<td>37.5 µg</td>
<td>Pantothenic acid</td>
<td>1.25 mg</td>
</tr>
<tr>
<td>Sodium</td>
<td>200 mg</td>
<td>Potassium</td>
<td>370 mg</td>
</tr>
<tr>
<td>Chloride</td>
<td>340 mg</td>
<td>Calcium</td>
<td>125 mg</td>
</tr>
<tr>
<td>Magnesium</td>
<td>50 mg</td>
<td>Iodine</td>
<td>18.8 µg</td>
</tr>
<tr>
<td>Manganese</td>
<td>0.62 mg</td>
<td>Copper</td>
<td>0.25 mg</td>
</tr>
<tr>
<td>Zinc</td>
<td>2.82 mg</td>
<td>Iron</td>
<td>2.25 mg</td>
</tr>
</tbody>
</table>
### Appendix III

**Details of patients recruited into the feasibility study**

<table>
<thead>
<tr>
<th>Pt No</th>
<th>Initials</th>
<th>Age</th>
<th>NRS</th>
<th>Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>DA</td>
<td>81</td>
<td>11</td>
<td>S-C</td>
</tr>
<tr>
<td>02</td>
<td>FC</td>
<td>84</td>
<td>8.5</td>
<td>S-C</td>
</tr>
<tr>
<td>03</td>
<td>MP</td>
<td>85</td>
<td>10</td>
<td>S-C</td>
</tr>
<tr>
<td>04</td>
<td>HW</td>
<td>83</td>
<td>11</td>
<td>S-C</td>
</tr>
<tr>
<td>05</td>
<td>MB</td>
<td>84</td>
<td>13</td>
<td>S-C</td>
</tr>
<tr>
<td>06</td>
<td>MS</td>
<td>99</td>
<td>11</td>
<td>S-C</td>
</tr>
<tr>
<td>07</td>
<td>CR</td>
<td>81</td>
<td>11</td>
<td>S-C</td>
</tr>
<tr>
<td>08</td>
<td>VS</td>
<td>82</td>
<td>9.5</td>
<td>S-C</td>
</tr>
<tr>
<td>09</td>
<td>GM</td>
<td>87</td>
<td>10</td>
<td>S-C</td>
</tr>
<tr>
<td>10</td>
<td>DT</td>
<td>87</td>
<td>9</td>
<td>S-C</td>
</tr>
<tr>
<td>11</td>
<td>FM</td>
<td>83</td>
<td>9</td>
<td>S-C</td>
</tr>
<tr>
<td>12</td>
<td>MG</td>
<td>74</td>
<td>8</td>
<td>N-NC</td>
</tr>
<tr>
<td>13</td>
<td>EP</td>
<td>106</td>
<td>8</td>
<td>N-CP</td>
</tr>
<tr>
<td>14</td>
<td>KB</td>
<td>80</td>
<td>10</td>
<td>N-CP</td>
</tr>
<tr>
<td>15</td>
<td>EH</td>
<td>85</td>
<td>12</td>
<td>N-CP</td>
</tr>
<tr>
<td>16</td>
<td>BS</td>
<td>67</td>
<td>8</td>
<td>N-CP</td>
</tr>
<tr>
<td>17</td>
<td>OB</td>
<td>92</td>
<td>8</td>
<td>N-CP</td>
</tr>
<tr>
<td>18</td>
<td>LH</td>
<td>88</td>
<td>8</td>
<td>N-CP</td>
</tr>
<tr>
<td>19</td>
<td>BB</td>
<td>70</td>
<td>8</td>
<td>NS-CP</td>
</tr>
<tr>
<td>20</td>
<td>MR</td>
<td>70</td>
<td>8</td>
<td>NS-CP</td>
</tr>
<tr>
<td>21</td>
<td>MW</td>
<td>82</td>
<td>9</td>
<td>NS-CP</td>
</tr>
<tr>
<td>22</td>
<td>MC</td>
<td>89</td>
<td>8</td>
<td>NS-CP</td>
</tr>
<tr>
<td>23</td>
<td>BL</td>
<td>92</td>
<td>10</td>
<td>NS-CP</td>
</tr>
<tr>
<td>24</td>
<td>DT</td>
<td>60</td>
<td>8</td>
<td>NS-CP</td>
</tr>
<tr>
<td>25</td>
<td>JN</td>
<td>73</td>
<td>8</td>
<td>NS-CP</td>
</tr>
<tr>
<td>26</td>
<td>SR</td>
<td>81</td>
<td>11</td>
<td>NS-CP</td>
</tr>
<tr>
<td>27</td>
<td>EL</td>
<td>91</td>
<td>9.5</td>
<td>NS-CP</td>
</tr>
<tr>
<td>28</td>
<td>EK</td>
<td>84</td>
<td>11.5</td>
<td>NS-CP</td>
</tr>
<tr>
<td>29</td>
<td>MM</td>
<td>87</td>
<td>12</td>
<td>NS-CP</td>
</tr>
<tr>
<td>30</td>
<td>FE</td>
<td>92</td>
<td>13</td>
<td>NS-NCP</td>
</tr>
<tr>
<td>31</td>
<td>GS</td>
<td>93</td>
<td>14</td>
<td>NS-NCP</td>
</tr>
<tr>
<td>32</td>
<td>ME</td>
<td>74</td>
<td>9</td>
<td>NS-NCP</td>
</tr>
<tr>
<td>33</td>
<td>GB</td>
<td>88</td>
<td>8</td>
<td>NS-NCP</td>
</tr>
<tr>
<td>34</td>
<td>FT</td>
<td>90</td>
<td>11</td>
<td>NS-NCP</td>
</tr>
<tr>
<td>35</td>
<td>BG</td>
<td>72</td>
<td>8</td>
<td>NS-NCP</td>
</tr>
<tr>
<td>36</td>
<td>IS</td>
<td>85</td>
<td>13</td>
<td>NS-NCP</td>
</tr>
</tbody>
</table>
Appendix
IV
**Appendix IV**

Table A4.1

**Nutritional composition of the supplements offered to the patients in the long term follow up study**

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Fortimel (200ml)</th>
<th>Protipudding (150g)</th>
<th>Liquisorb (500ml)</th>
<th>Enteral 250 (250ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Energy (Kcal)</td>
<td>200</td>
<td>197</td>
<td>500</td>
<td>250</td>
</tr>
<tr>
<td>Energy (Kj)</td>
<td>838</td>
<td>833</td>
<td>2100</td>
<td>1047</td>
</tr>
<tr>
<td>Protein (g)</td>
<td>19.4</td>
<td>15.3</td>
<td>20</td>
<td>8</td>
</tr>
<tr>
<td>Fat (g)</td>
<td>4.2</td>
<td>4.5</td>
<td>20</td>
<td>8</td>
</tr>
<tr>
<td>Carbohydrate (g)</td>
<td>20.8</td>
<td>24</td>
<td>59</td>
<td>40</td>
</tr>
</tbody>
</table>
Appendix IV

Details of patients recruited into the long term follow up study

<table>
<thead>
<tr>
<th>Patient No</th>
<th>Initials</th>
<th>Age</th>
<th>NRS</th>
<th>Subgroup</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>ES</td>
<td>82</td>
<td>12.5</td>
<td>S-C</td>
</tr>
<tr>
<td>02</td>
<td>VC</td>
<td>77</td>
<td>11</td>
<td>S-C</td>
</tr>
<tr>
<td>03</td>
<td>LT</td>
<td>79</td>
<td>11</td>
<td>S-C</td>
</tr>
<tr>
<td>04</td>
<td>KA</td>
<td>75</td>
<td>8.5</td>
<td>S-C</td>
</tr>
<tr>
<td>05</td>
<td>MB</td>
<td>69</td>
<td>16</td>
<td>S-C</td>
</tr>
<tr>
<td>06</td>
<td>WL</td>
<td>68</td>
<td>8</td>
<td>S-C</td>
</tr>
<tr>
<td>07</td>
<td>IC</td>
<td>75</td>
<td>11</td>
<td>S-C</td>
</tr>
<tr>
<td>08</td>
<td>MR</td>
<td>75</td>
<td>8</td>
<td>S-C</td>
</tr>
<tr>
<td>09</td>
<td>MH</td>
<td>85</td>
<td>12</td>
<td>S-C</td>
</tr>
<tr>
<td>10</td>
<td>KB</td>
<td>83</td>
<td>8.5</td>
<td>S-C</td>
</tr>
<tr>
<td>11</td>
<td>MR</td>
<td>85</td>
<td>13</td>
<td>S-C</td>
</tr>
<tr>
<td>12</td>
<td>FE</td>
<td>81</td>
<td>11</td>
<td>S-C</td>
</tr>
<tr>
<td>13</td>
<td>GB</td>
<td>72</td>
<td>14.5</td>
<td>S-C</td>
</tr>
<tr>
<td>14</td>
<td>MS</td>
<td>93</td>
<td>10</td>
<td>S-NC</td>
</tr>
<tr>
<td>15</td>
<td>MT</td>
<td>80</td>
<td>13</td>
<td>S-NC</td>
</tr>
<tr>
<td>16</td>
<td>AC</td>
<td>82</td>
<td>12</td>
<td>S-NC</td>
</tr>
<tr>
<td>17</td>
<td>AE</td>
<td>88</td>
<td>17</td>
<td>S-NC</td>
</tr>
<tr>
<td>18</td>
<td>AA</td>
<td>91</td>
<td>12</td>
<td>S-NC</td>
</tr>
<tr>
<td>19</td>
<td>EM</td>
<td>83</td>
<td>9</td>
<td>S-NC</td>
</tr>
<tr>
<td>20</td>
<td>MR</td>
<td>82</td>
<td>8</td>
<td>S-NC</td>
</tr>
<tr>
<td>21</td>
<td>EW</td>
<td>77</td>
<td>11.5</td>
<td>S-NC</td>
</tr>
<tr>
<td>22</td>
<td>ES</td>
<td>86</td>
<td>11</td>
<td>NS-CP</td>
</tr>
<tr>
<td>23</td>
<td>CL</td>
<td>89</td>
<td>9</td>
<td>NS-CP</td>
</tr>
<tr>
<td>24</td>
<td>MM</td>
<td>83</td>
<td>15</td>
<td>NS-CP</td>
</tr>
<tr>
<td>25</td>
<td>NP</td>
<td>81</td>
<td>9</td>
<td>NS-CP</td>
</tr>
<tr>
<td>26</td>
<td>EA</td>
<td>85</td>
<td>10</td>
<td>NS-CP</td>
</tr>
<tr>
<td>27</td>
<td>RS</td>
<td>91</td>
<td>12</td>
<td>NS-CP</td>
</tr>
<tr>
<td>28</td>
<td>RL</td>
<td>91</td>
<td>14</td>
<td>NS-CP</td>
</tr>
<tr>
<td>29</td>
<td>GP</td>
<td>90</td>
<td>10</td>
<td>NS-CP</td>
</tr>
<tr>
<td>30</td>
<td>WE</td>
<td>83</td>
<td>12</td>
<td>NS-CP</td>
</tr>
<tr>
<td>31</td>
<td>PC</td>
<td>70</td>
<td>10</td>
<td>NS-CP</td>
</tr>
<tr>
<td>32</td>
<td>VM</td>
<td>80</td>
<td>8</td>
<td>NS-CP</td>
</tr>
<tr>
<td>33</td>
<td>PM</td>
<td>78</td>
<td>10.5</td>
<td>NS-CP</td>
</tr>
<tr>
<td>34</td>
<td>AC</td>
<td>75</td>
<td>13</td>
<td>NS-CP</td>
</tr>
<tr>
<td>35</td>
<td>NM</td>
<td>72</td>
<td>14</td>
<td>NS-NCP</td>
</tr>
<tr>
<td>36</td>
<td>DB</td>
<td>87</td>
<td>9</td>
<td>NS-NCP</td>
</tr>
<tr>
<td>37</td>
<td>MF</td>
<td>86</td>
<td>10</td>
<td>NS-NCP</td>
</tr>
<tr>
<td>38</td>
<td>VB</td>
<td>90</td>
<td>11</td>
<td>NS-NCP</td>
</tr>
<tr>
<td>39</td>
<td>BF</td>
<td>93</td>
<td>10</td>
<td>NS-NCP</td>
</tr>
<tr>
<td>40</td>
<td>LL</td>
<td>82</td>
<td>11</td>
<td>NS-NCP</td>
</tr>
<tr>
<td>41</td>
<td>NF</td>
<td>76</td>
<td>8.5</td>
<td>NS-NCP</td>
</tr>
<tr>
<td>42</td>
<td>MC</td>
<td>83</td>
<td>15</td>
<td>NS-NCP</td>
</tr>
</tbody>
</table>
Appendix IV

Table A4.2

Volume of supplements consumed by individual patients in the S-C sub-group and the reason given for not wishing to continue.

<table>
<thead>
<tr>
<th>Pt No / Init</th>
<th>Supplements first consumed (days post-disch)</th>
<th>Supplements sampled</th>
<th>Volume of supplement consumed</th>
<th>Reason given for not wishing to continue</th>
</tr>
</thead>
<tbody>
<tr>
<td>14 / MS</td>
<td>2</td>
<td>Liquisorb</td>
<td>Approx 150 mls for one day</td>
<td>&quot;Too sweet&quot;</td>
</tr>
<tr>
<td>15 / MT</td>
<td>2</td>
<td>Liquisorb</td>
<td>Aver 350 mls/day over 4 days</td>
<td>&quot;Makes me feel sick&quot;</td>
</tr>
<tr>
<td>16 / AC</td>
<td>4</td>
<td>Fortimel</td>
<td>Few sips for 3 days</td>
<td>&quot;Too sweet&quot;</td>
</tr>
<tr>
<td>17 / AE</td>
<td>4</td>
<td>Fortimel Liquisorb</td>
<td>Aver 150 mls/day over 3 days</td>
<td>&quot;Made me feel sick&quot;</td>
</tr>
<tr>
<td>18 / AA</td>
<td>4</td>
<td>Fortimel Liquisorb</td>
<td>Approx 150 mls/day for 4 days</td>
<td>Patient became too drowsy after CVA and died.</td>
</tr>
<tr>
<td>19 / EM</td>
<td>4</td>
<td>Liquisorb</td>
<td>200 mls/day for 9 days</td>
<td>&quot;Too rich&quot;</td>
</tr>
<tr>
<td>20 / MR</td>
<td>2</td>
<td>Fortimel Liquisorb</td>
<td>Few sips each day for 14 days</td>
<td>&quot;Don't want to drink&quot;</td>
</tr>
<tr>
<td>21 / EW</td>
<td>4</td>
<td>Fortimel Liquisorb</td>
<td>Few sips each day for 6 days</td>
<td>&quot;Not keen&quot;</td>
</tr>
<tr>
<td>Mean (sd)</td>
<td>3.25 (± 1.0)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median (25th, 75th)</td>
<td>4 (2, 4)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Appendix IV

#### Table A4.3.i

*Daily protein and energy intakes from normal foods (24 hour dietary recalls) of individual patients in the S-C subgroup*

<table>
<thead>
<tr>
<th>Pt no/Init</th>
<th>Age (years)</th>
<th>24 hour Protein intake (g)</th>
<th>24 hour Energy intake (kcal)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Hosp 4wks PD 6mths PD Hosp 4wks PD 6mths PD</td>
<td></td>
</tr>
<tr>
<td>01/ES</td>
<td>82</td>
<td>86.7             68.0     61.2</td>
<td>1087          1080 1097</td>
</tr>
<tr>
<td>02/VC</td>
<td>77</td>
<td>53.8             55.3     62.4</td>
<td>1523          1194 2132</td>
</tr>
<tr>
<td>03/LT</td>
<td>79</td>
<td>42.0             32.1     --</td>
<td>1299          324   --</td>
</tr>
<tr>
<td>04/KA</td>
<td>75</td>
<td>--               43.0     74.4</td>
<td>--            1180 1486</td>
</tr>
<tr>
<td>05/MB</td>
<td>69</td>
<td>--               37.8     55.0</td>
<td>--            1208 1208</td>
</tr>
<tr>
<td>06/WL</td>
<td>68</td>
<td>75.0             62.5     62.2</td>
<td>1847          1248 1405</td>
</tr>
<tr>
<td>07/IC</td>
<td>75</td>
<td>72.7             64.2     49.4</td>
<td>1247          1880 1607</td>
</tr>
<tr>
<td>08/MR</td>
<td>75</td>
<td>63.3             81.0     80.0</td>
<td>1530          1852 1366</td>
</tr>
<tr>
<td>09/MH</td>
<td>85</td>
<td>73.4             24.4     33.8</td>
<td>1110          1273 751</td>
</tr>
<tr>
<td>10/KB</td>
<td>83</td>
<td>70.7             69.9     61.4</td>
<td>1386          1879 1502</td>
</tr>
<tr>
<td>11/MR</td>
<td>85</td>
<td>48.4             44.2     57.2</td>
<td>1241          1409 1044</td>
</tr>
<tr>
<td>12/FE</td>
<td>81</td>
<td>55.5             64.3     48.4</td>
<td>1606          1469 1705</td>
</tr>
<tr>
<td>13/GB</td>
<td>72</td>
<td>52.6             69.9     65.0</td>
<td>1400          1298 1449</td>
</tr>
<tr>
<td>Mean (sd)</td>
<td>77.4</td>
<td>(± 5.7)</td>
<td>61.8             55.1     59.2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(± 11.4)</td>
<td>(± 17.2)</td>
</tr>
<tr>
<td>Median</td>
<td>(25,75)</td>
<td>63.3</td>
<td>62.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(52.5, 72.7)</td>
<td>(40.4, 69.0)</td>
</tr>
</tbody>
</table>
### Table A4.3.ii

**Daily protein and energy intakes from normal foods**
*(24 hour dietary recalls) of individual patients in the S-NC sub group*

<table>
<thead>
<tr>
<th>Pt no/Init</th>
<th>Age (years)</th>
<th>24 hour Protein intake (g)</th>
<th>24 hour Energy intake (kcals)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Hosp</td>
<td>4 wks PD</td>
</tr>
<tr>
<td>14/MS</td>
<td>93</td>
<td>34.6</td>
<td>38.5</td>
</tr>
<tr>
<td>15/MT</td>
<td>80</td>
<td>53.9</td>
<td>70.0</td>
</tr>
<tr>
<td>16/AC</td>
<td>82</td>
<td>61.8</td>
<td>49.5</td>
</tr>
<tr>
<td>17/AE</td>
<td>88</td>
<td>49.3</td>
<td>46.2</td>
</tr>
<tr>
<td>18/AA</td>
<td>91</td>
<td>18.8</td>
<td>Died</td>
</tr>
<tr>
<td>19/EM</td>
<td>83</td>
<td>53.1</td>
<td>66.8</td>
</tr>
<tr>
<td>20/MR</td>
<td>82</td>
<td>75.1</td>
<td>54.1</td>
</tr>
<tr>
<td>21/EW</td>
<td>77</td>
<td>55.2</td>
<td>69.3</td>
</tr>
<tr>
<td>Mean (sd)</td>
<td></td>
<td>84.5</td>
<td>± 11.3</td>
</tr>
<tr>
<td>Median</td>
<td></td>
<td>54.6</td>
<td>(42.0, 60.0)</td>
</tr>
</tbody>
</table>

xlv
### Appendix IV

Daily protein and energy intakes from normal foods
(24 hour dietary recalls) of individual patients
in the NS-CP sub group

<table>
<thead>
<tr>
<th>Pt no/Init</th>
<th>Age (years)</th>
<th>24 hour Protein intake (g)</th>
<th>24 hour Energy intake (kcals)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Hosp</td>
<td>4 wks PD</td>
</tr>
<tr>
<td>22/ES</td>
<td>86</td>
<td>-</td>
<td>69.4</td>
</tr>
<tr>
<td>23/CL</td>
<td>89</td>
<td>-</td>
<td>6.5</td>
</tr>
<tr>
<td>24/MM</td>
<td>83</td>
<td>7.4</td>
<td>Died</td>
</tr>
<tr>
<td>25/NP</td>
<td>81</td>
<td>4.0</td>
<td>25.9</td>
</tr>
<tr>
<td>26/EA</td>
<td>85</td>
<td>100.1</td>
<td>55.9</td>
</tr>
<tr>
<td>27/RS</td>
<td>91</td>
<td>35.5</td>
<td>Died</td>
</tr>
<tr>
<td>28/RL</td>
<td>91</td>
<td>15.0</td>
<td>18.6</td>
</tr>
<tr>
<td>29/GP</td>
<td>90</td>
<td>16.8</td>
<td>75.2</td>
</tr>
<tr>
<td>30/WE</td>
<td>83</td>
<td>41.8</td>
<td>51.2</td>
</tr>
<tr>
<td>31/PC</td>
<td>70</td>
<td>47.9</td>
<td>49.8</td>
</tr>
<tr>
<td>32/VM</td>
<td>80</td>
<td>29.6</td>
<td>36.8</td>
</tr>
<tr>
<td>33/PM</td>
<td>78</td>
<td>90.4</td>
<td>67.8</td>
</tr>
<tr>
<td>34/AC</td>
<td>75</td>
<td>27.9</td>
<td>20.1</td>
</tr>
<tr>
<td>Mean (sd)</td>
<td></td>
<td>85.2</td>
<td>37.9</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(+ 6.4)</td>
<td>(+ 81.6)</td>
</tr>
<tr>
<td>Median (25th, 75th)</td>
<td>29.6</td>
<td>49.8</td>
<td>63.7</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(25.0, 47.9)</td>
<td>(20.1, 59.4)</td>
</tr>
</tbody>
</table>
### Appendix IV

**Daily protein and energy intakes from normal foods**

*(24 hour dietary recalls) of individual patients in the NS-NCP sub group*

<table>
<thead>
<tr>
<th>Pt no/ Init</th>
<th>Age (years)</th>
<th>24 hour Protein intake (g)</th>
<th>24 hour Energy intake (kcal)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Hosp</td>
<td>4 wks PD</td>
</tr>
<tr>
<td>35 / NM</td>
<td>72</td>
<td>56.7</td>
<td>71.3</td>
</tr>
<tr>
<td>36 / DB</td>
<td>87</td>
<td>47.9</td>
<td>51.1</td>
</tr>
<tr>
<td>37 / MF</td>
<td>86</td>
<td>95.3</td>
<td>63.6</td>
</tr>
<tr>
<td>38 / VB</td>
<td>90</td>
<td>39.0</td>
<td>55.5</td>
</tr>
<tr>
<td>39 / BF</td>
<td>93</td>
<td>49.4</td>
<td>74.5</td>
</tr>
<tr>
<td>40 / LL</td>
<td>82</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>41 / NF</td>
<td>76</td>
<td>63.3</td>
<td>49.1</td>
</tr>
<tr>
<td>42 / MC</td>
<td>83</td>
<td>67.3</td>
<td>47.6</td>
</tr>
</tbody>
</table>

Mean (sd)
- 83.6 (± 7.0)
- 59.8 (± 18.4)
- 58.9 (± 10.1)
- 63.8 (± 30.6)
- 1473 (± 161)
- 1411 (± 222)
- 1417 (± 648)

Median (25th, 75th)
- 56.7 (47.9, 67.3)
- 56.9 (60.1, 67.5)
- 67.7 (38.9, 80.8)
- 1450 (1390, 1584)
- 1438 (1272, 1558)
- 1380 (947, 2037)
Appendix V
### Table A5.1  
**NUTRITIONAL COMPOSITION OF FORTISIP (Energy plus)**

*average composition per 200 ml carton*

<table>
<thead>
<tr>
<th>NUTRIENT</th>
<th>UNITS</th>
<th>COMPOSITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Energy</td>
<td>kcal (kJ)</td>
<td>360 (1500)</td>
</tr>
<tr>
<td>Protein</td>
<td>g (% energy)</td>
<td>30 (135%)</td>
</tr>
<tr>
<td>Fat</td>
<td>g (% energy)</td>
<td>35 (39%)</td>
</tr>
<tr>
<td>Carbohydrate (Total)</td>
<td>g (% energy)</td>
<td>35.8 (48%)</td>
</tr>
<tr>
<td>Water</td>
<td>ml</td>
<td>197</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>VITAMINS</th>
<th>UNITS</th>
<th>COMPOSITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vit A</td>
<td>mg (iu)</td>
<td>0.14 (420)</td>
</tr>
<tr>
<td>Vit D</td>
<td>mg (iu)</td>
<td>1 (40)</td>
</tr>
<tr>
<td>Vit E</td>
<td>mg (iu)</td>
<td>6.3 (70)</td>
</tr>
<tr>
<td>Vit C</td>
<td>mg</td>
<td>10.0</td>
</tr>
<tr>
<td>Vit B1</td>
<td>mg</td>
<td>0.14</td>
</tr>
<tr>
<td>Vit B2</td>
<td>mg</td>
<td>0.2</td>
</tr>
<tr>
<td>Nitinol (Vit B3)</td>
<td>mg</td>
<td>2.9</td>
</tr>
<tr>
<td>Vit B12</td>
<td>mg</td>
<td>0.2</td>
</tr>
<tr>
<td>Folic acid</td>
<td>mg</td>
<td>50</td>
</tr>
<tr>
<td>Vit B6</td>
<td>mg</td>
<td>0.4</td>
</tr>
<tr>
<td>Pantethenic acid</td>
<td>mg</td>
<td>1</td>
</tr>
<tr>
<td>Biotin</td>
<td>mg</td>
<td>50</td>
</tr>
<tr>
<td>Mecobalamin</td>
<td>mg</td>
<td>46</td>
</tr>
<tr>
<td>Choline</td>
<td>mg</td>
<td>96</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MINERALS</th>
<th>UNITS</th>
<th>COMPOSITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium</td>
<td>mg (mmol)</td>
<td>160 (7)</td>
</tr>
<tr>
<td>Potassium</td>
<td>mg (mmol)</td>
<td>300 (7.6)</td>
</tr>
<tr>
<td>Calcium</td>
<td>mg (mmol)</td>
<td>100 (2.5)</td>
</tr>
<tr>
<td>Phosphorus</td>
<td>mg (mmol)</td>
<td>100 (3.3)</td>
</tr>
<tr>
<td>Magnesium</td>
<td>mg (mmol)</td>
<td>30 (1.3)</td>
</tr>
<tr>
<td>Iron</td>
<td>mg</td>
<td>2.0</td>
</tr>
<tr>
<td>Zinc</td>
<td>mg</td>
<td>1.4</td>
</tr>
<tr>
<td>Manganese</td>
<td>mg</td>
<td>0.5</td>
</tr>
<tr>
<td>Copper</td>
<td>mg</td>
<td>0.2</td>
</tr>
<tr>
<td>Chloride</td>
<td>mg (mmol)</td>
<td>100 (4.5)</td>
</tr>
<tr>
<td>Iodide</td>
<td>mg</td>
<td>12</td>
</tr>
</tbody>
</table>

Non protein calorie:Nitrogen ratio: 167:1

Energy density: 1.5 kcal/ml
Appendix V

Details of patients recruited into NEP Study

<table>
<thead>
<tr>
<th>Pt No</th>
<th>Age</th>
<th>NRS</th>
<th>Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>75</td>
<td>16</td>
<td>NEP C</td>
</tr>
<tr>
<td>2</td>
<td>60</td>
<td>11</td>
<td>NEP C</td>
</tr>
<tr>
<td>3</td>
<td>59</td>
<td>9</td>
<td>NEP C</td>
</tr>
<tr>
<td>11</td>
<td>82</td>
<td>11</td>
<td>NEP C</td>
</tr>
<tr>
<td>20</td>
<td>76</td>
<td>7</td>
<td>NEP C</td>
</tr>
<tr>
<td>24</td>
<td>67</td>
<td>10</td>
<td>NEP C</td>
</tr>
<tr>
<td>25</td>
<td>66</td>
<td>7</td>
<td>NEP C</td>
</tr>
<tr>
<td>5</td>
<td>84</td>
<td>10</td>
<td>NEP NC</td>
</tr>
<tr>
<td>7</td>
<td>76</td>
<td>11</td>
<td>NEP NC</td>
</tr>
<tr>
<td>8</td>
<td>76</td>
<td>8</td>
<td>NEP NC</td>
</tr>
<tr>
<td>16</td>
<td>70</td>
<td>16</td>
<td>NEP NC</td>
</tr>
<tr>
<td>17</td>
<td>64</td>
<td>9</td>
<td>NEP NC</td>
</tr>
<tr>
<td>18</td>
<td>74</td>
<td>8</td>
<td>NEP NC</td>
</tr>
<tr>
<td>21</td>
<td>59</td>
<td>9</td>
<td>NEP NC</td>
</tr>
<tr>
<td>6</td>
<td>83</td>
<td>9</td>
<td>N-NEP C</td>
</tr>
<tr>
<td>10</td>
<td>70</td>
<td>9</td>
<td>N-NEP C</td>
</tr>
<tr>
<td>12</td>
<td>74</td>
<td>7</td>
<td>N-NEP C</td>
</tr>
<tr>
<td>23</td>
<td>66</td>
<td>7</td>
<td>N-NEP C</td>
</tr>
<tr>
<td>4</td>
<td>69</td>
<td>7</td>
<td>N-NEP NC</td>
</tr>
<tr>
<td>9</td>
<td>73</td>
<td>10</td>
<td>N-NEP NC</td>
</tr>
<tr>
<td>13</td>
<td>82</td>
<td>17</td>
<td>N-NEP NC</td>
</tr>
<tr>
<td>14</td>
<td>71</td>
<td>9</td>
<td>N-NEP NC</td>
</tr>
<tr>
<td>15</td>
<td>67</td>
<td>8</td>
<td>N-NEP NC</td>
</tr>
<tr>
<td>19</td>
<td>72</td>
<td>8</td>
<td>N-NEP NC</td>
</tr>
<tr>
<td>22</td>
<td>72</td>
<td>10</td>
<td>N-NEP NC</td>
</tr>
</tbody>
</table>
Appendix V

NUTRITION AND ILLNESS

We would be very grateful if you could answer the following questions as part of our research programme on nutrition and illness. The answers are in strict confidence and will in no way influence your course of treatment.

1. Do you read nutritional information on food labels?
   - Yes always
   - Yes often
   - Sometimes
   - Hardly ever
   - Never

2. Do you read articles about food and health in magazines, or listen to them on the T.V. and Radio?
   - Yes, I make a point of reading/listening
   - Often if I know about them
   - Sometimes
   - Hardly ever
   - No, I'm not interested

3. Do you take vitamin/mineral supplements?
   - Yes every day
   - Quite regularly
   - Sometimes
   - Only occasionally
   - Never

4. Do you consciously choose the 'healthier' alternative foods (e.g. low fat milk, sunflower margarine, wholemeal bread etc.)
   - Yes always
   - Usually but not always
   - Sometimes
   - Occasionally
   - Never

5. Do you make a conscious effort to maintain your weight within reasonable limits? (Both losing and gaining).
   - Yes, I keep a strict eye on my weight
   - Only if I lose or gain a large amount
   - Doesn't really bother me
   - Never

6. What do you think about your requirement for nutrients (food) now that you are in hospital, compared to when you were at home?
   - I need much less
   - A little more in hospital
   - About the same
   - A bit less
   - Now

xix
7. How do you feel about your health throughout your life?

| I've been very lucky, had an excellent health, & got over illness very quickly | Had less illness than average, recovered quite well | Had more illness than average, took a long time to recover | Very unlucky had one thing after another |

8. How do you feel about your future?

| I will get better and be able to carry on with my normal life soon | I will recover, but I know it will take time | Not sure yet to say | I know I will recover, but it will never be able to do the things I did before I came into hospital |

9. How do you feel about your life in general?

| Very happy | Happy & contented | "Just live it" | Little Unhappy | Very Unhappy |

10. How do you feel about your ability to cope once you get home?

| Very confident | Fairly confident but I know I will manage | Apprehensive but I know I will manage in the end | Very anxious I don't think I'll be able to manage |

Thank you very much for your help.
NOTES TO ACCOMPANY LECTURE I:
DIETARY SUPPLEMENTS - THE RSCH STUDY

Background

Sip-feed supplements offer a simple and effective method of nutritional support in elderly hospital patients, many of whom are unable or unwilling to eat sufficient normal foods to meet their nutritional requirements. Our studies, carried out at the RSCH Guildford, have shown that supplements taken in hospital by patients after orthopaedic surgery, prevent loss of body fat (triceps skinfold thickness), and muscle mass (mid upper arm muscle circumference). When taken for longer periods after discharge from hospital, the supplements were shown to promote weight gain and significantly reduce duration of stay in convalescence. Other clinical outcome criteria are currently being evaluated, but preliminary analysis suggests that patients who comply with the supplement regimen also show other clinical improvements not seen in the control group of patients who have not received supplements. If these data prove correct, then they suggest that prolonged use of supplements in at-risk patients, have advantages not only in terms of improved nutritional status and quality of life, but also in terms of reduced complication and readmission rates, and thereby cost of aftercare.

However, compliance to sip-feed supplements in our studies has been poor, despite offering a range of supplements with different flavours and textures. 40% of patients offered the supplements either refused on first offer or discontinued their use after 2-3 days. Refusal to accept the supplement may reflect behavioural and attitude characteristics of individual patients. However, the nutritional knowledge of nursing and auxiliary staff who can encourage uptake of the supplement throughout the day, may also be a determinant of patient compliance.

In this study it is proposed to investigate the influence on supplement compliance, of providing nutrition education and detailed information on the potential value of nutritional supplements, to nursing and auxiliary staff concerned with the care of elderly patients admitted for surgery. Patients offered supplements will also be given more detailed information appropriate to
supplement drinks. Effects of these procedures on supplement compliance will be evaluated by comparison of compliance rates in patients in a paired ward in which no support programme will be used.

**Experimental Design**

The study group will comprise all elderly (>60 years) female patients admitted for surgery to two wards at the RSCH Guildford. Patients will be recruited if they have been admitted for surgical procedure which requires an average duration of stay of 8 days or more. Patients will be asked to participate in the study and will be free to withdraw at any time if they wish to do so.

A Nutritional Risk Questionnaire (NRQ) will be administered to all patients who agree to participate. Patients achieving a score <8 will be classified as low-risk and will not be investigated further. Patients achieving a score >8 will be classified as high risk and will be asked to take 2 cartons of Fortisip per day during their period of stay in hospital, (600 kcals, 20g protein) beginning on the first day of resumption of oral intake after surgery.

In one ward (Bramshott), nurses will receive a programme of nutrition education (details later) and patients will receive detailed information and encouragement to continue with the product. In the other ward (Ewhurst), standard procedures currently practised on the ward will be applied. The nutritionist will visit all patients daily to assess supplement intake and 24 hour dietary recall measurements will be made over 3 days. Serum albumin and retinol binding protein concentrations, triceps skinfold thickness and mid upper arm muscle circumference measurements will be made on admission and at discharge, to provide objective indices of nutritional status. Mental and muscle function measurements will be made four days after surgery.

Information on patients attitudes to the supplement, reasons for discontinuation, and willingness to continue with the supplement after discharge if offered, will be rated, and a compliance score achieved.
NOTES TO ACCOMPANY LECTURE II:
HOW DO I RECOGNISE A NUTRITIONALLY AT RISK PATIENT?

There are many methods available for the assessment of nutritional status, each with their own advantages and limitations, and consequently there is no single, universally accepted gold standard. For the purpose of research, screening procedures often involve a combination of parameters, in order to identify the nutritionally at risk patient.

These are some of the main methods used in assessments:

**Diet History**

**Anthropometry:**

- Body Weight
- Triceps skinfold thickness (TSF)
- Mid upper arm muscle circumference (MUAMC)

**Clinical Examination:**

These methods are often time consuming, expensive, require trained personnel to administer and often involve a time delay in results. For these reasons, it would be impractical to employ such methods for routine ward screening procedures to be carried out on all patients admitted to hospital.

Although patients may not show obvious signs of malnutrition on admission to hospital, their nutritional status may already be compromised to varying degrees. Such patients, often unable to meet nutritional needs whilst in hospital, are in danger of suffering the consequences of malnutrition and need to be identified quickly, in order that preventative measures can be taken in the form of nutritional support.
Many factors increase the likelihood of a patient being nutritionally 'at risk'. By identifying each of the risk factors applicable to a patient, a semi objective score of relative risk can be obtained. (Most of the information required would be routinely recorded on the nursing core plan or would be revealed during the development of the close relationship between nurse and patient.) This score can then serve as a guideline in planning any nutritional intervention, although should be used with some degree of flexibility.

A copy of the Nutrition Risk Questionnaire as used in the RSCH study has been enclosed. This was designed for specific use with elderly orthopaedic patients, but similar questionnaires could be designed for use with other groups of patients.

Thus, a combination of a simple, tick list questionnaire to assess nutritional risk, with an admission weight and any routinely performed blood biochemistry results can be used as routine screening procedures. Regular weight assessments, blood results and subjective food intake assessments can be used to monitor and evaluate the effectiveness of the nutritional support regime. Comments should be recorded either on the daily care plan, or a separate nutritional assessment sheet, and adjustments made as necessary.
NOTES TO ACCOMPANY LECTURE III

HOW CAN SPECIALISED FEEDING AID THE CONVALESCING PATIENT

The reported incidence of malnutrition in hospital patients ranges from 19% - 80%, according to the group of patients studied. Not only has it been shown that many patients are malnourished on admission to hospital, but it has also been demonstrated that up to 30% develop their malnutrition after admission, i.e. iatrogenic malnutrition (Bistrian et al 1974, Weinsier et al 1979).

Underlying Cause of Iatrogenic Malnutrition

The Condition Itself May Cause:

- Reduced Appetite (anorexia)
- Impaired absorption/digestion
- Increased requirements.

Circumstantial Factors:

- Pain
- Anxiety
- Change of routine
- Unfamiliar foods
- Drugs.
- Failure to record weight periodically
- Failure to observe food intake
- Failure to recognise need for nutritional support
- Delay in implementing support
- Inappropriate support (e.g. prolonged use of glucose and saline post-operatively).

Consequences of Malnutrition

During malnutrition, all human organs will show a reduction in mass, with the exception of the brain. Tissues which undergo rapid protein turnover are particularly affected, for example the gut will suffer a substantial mass loss after only a short period of inadequate nutrition. Consequently, mucosal atrophy is seen, which, coupled with a decrease in gut motility, will lead to malabsorption and maldigestion, thus exacerbating the problem still further.
Some Effects of Malnutrition:

- ↑ tendency to infections
- Delayed wound healing
- Suture insufficiency
- Hypoproteinaemia
- ↓ motility of intestine
- Muscle weakness

↑ mortality
↑ morbidity
Prolonged hospitalization
Prolonged convalescence
↑ cost

Consequences of Delayed Nutritional Support

During total starvation, body reserves are depleted within about 40-50 days, but this can be 2-3 x faster, if accompanied by surgery or other trauma.

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Store (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbohydrate</td>
<td>&lt; 1</td>
</tr>
<tr>
<td>Protein</td>
<td>60-65</td>
</tr>
<tr>
<td>Fat</td>
<td>48-61</td>
</tr>
</tbody>
</table>

The Loss of Lean Body Mass (LBM)

In response to stress LBM is broken down and metabolised to produce energy. Also, muscle wasting due to inactivity occurs. As a consequence, the immune system becomes impaired and will inevitably lead to an increased susceptibility to infections. For example, secondary pneumonia as a cause of death is often a result of a combination of atrophy of the intercostal muscles and an impaired immunocompetence, both consequences of malnutrition.
Persistence and Long-Term Effects of Malnutrition

Linn, 1984 studied the long-term effects of malnutrition in 50 patients younger than 65 years and 22 older than 65 years. One year later, those patients who were initially malnourished, had more indicators of malnutrition than those patients who were well nourished at initial investigation. Thus the consequences of being malnourished during hospitalization, may have long lasting detrimental effects.

The Effects of Nutritional Support

A number of recent studies have demonstrated improvements in mortality and complication rates, in patients given nutritional support, compared with those receiving no such support.

For example, Mullen et al (1980) used a combination of nutritional parameters to formulate the Prognostic Nutritional Index (PNI). The high risk patients who received pre and post operative nutritional support, (in the form of TPN) demonstrated significantly reduced complication and mortality rates.

<table>
<thead>
<tr>
<th></th>
<th>Post-operative Complications</th>
<th>Mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Risk TPN</td>
<td>23%</td>
<td>9%</td>
</tr>
<tr>
<td>High Risk Control</td>
<td>56%</td>
<td>47%</td>
</tr>
</tbody>
</table>

What methods are available for the provision of nutritional support?

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ordinary food</td>
<td>May not be nutrient dense</td>
</tr>
<tr>
<td>Familiar</td>
<td></td>
</tr>
<tr>
<td>Relatively inexpensive</td>
<td>Bulky</td>
</tr>
</tbody>
</table>

xxvii
ii) **Sip-feed supplements**
- Convenient
- Nutrient dense
- Nutritionally balanced
- Less expensive (£1.20/d)
- Requires little nursing involvement

Problems if patient dislikes milky drinks
- compliance may be poor

iii) **Enteral Feeding (nasogastric tube feeding)**
- More control over intake
- More expensive (£10/d)
- Requires more nursing involvement
- Invasive
- Patients may remove NG tube

iv) **Parenteral Feeding (intravenous)**
- Essential in certain circumstances
- Invasive
- Even more expensive (£100/d)
- Hazardous (infection)
- Requires more nursing involvement
The Nutritional Support Programme

Screen patients to identify at risk individuals

Calculate Requirements

Select route of administration

Monitor intakes

Modify intake/route of administration as required

Monitor effects of therapy
e.g. weight change, albumin conc., general appearance and well being

* Nurses role particularly important at these stages.
Conclusion

Unfortunately malnutrition does exist in hospital patients today and can have serious detrimental effects on patients clinical course.

Early recognition of a potential nutritional problem and intervention of an appropriate Nutritional Support Programme are essential in order to optimise patient care and help prevent prolonged suffering. Once such a Programme has been implemented, to monitor the therapy is an important but often neglected part of the support. In all these stages the nurse is probably the single, most key personnel and whose involvement is vital for a successful outcome.
NOTES TO ACCOMPANY LECTURE IV

SPECIAL NUTRITIONAL PROBLEMS OF THE
ELDERLY ORTHOPAEDIC PATIENT

In Britain today deficiency diseases are not common, but they are found more frequently in old people than in any other section of the community. The reasons for the patient not being able to obtain a satisfactory diet are usually economic or social. (Refer to lecture notes II)

Many elderly people reduce their physical activity and so requirements for energy may be reduced. Requirements for vitamins and minerals, however, remain the same as they did in younger days but intakes of these nutrients are likely to be inadequate if the energy intake is less than 2000 kcals/day. Hence when infirmities restrict physical activity and so limit food intake, a change in the pattern of the diet may be needed in order to ensure adequate nutrient density.

The digestive and absorptive powers of the alimentary tract are well maintained in healthy elderly, yet in certain disease states or existing malnutrition, their ability to absorb and digest food is impaired. For various reasons, certain food groups may be omitted from the diets of the elderly resulting in inadequate intakes of certain nutrients. For example, the anaemias are common in elderly patients and their diets are often deficient in vitamin C.

Nutrients likely to be inadequate in the diets of elderly patients include:

Calories
Calcium
Iron
Vitamin D
Vitamin C
Folic Acid
Requirements of the elderly surgical patient.

Elderly patients admitted to hospital may therefore be in a poor state of nutrition prior to admission and poor appetites in hospital will mean that they may be unable to meet the extra nutritional demands imposed by trauma/surgery. When nutritional reserves are low, requirements high, and intakes low, the patient is in serious danger of suffering the consequences of malnutrition unless nutritional support is given.

The maintenance of good nutritional status in the hospitalised patient is a major aim of nursing care. This is particularly true when the patient is recovering from a severe wound, which may have arisen as the result of surgical procedures, accidental injury or systemic disease.

Nutrition and wound healing

Successful wound healing requires adequate provision of protein, carbohydrate, fat, vitamins, minerals and trace elements.

In particular, protein deficiency delays wound healing and produces a wound with diminished tensile strength (Steiger et al 1973). The presence of all the essential amino acids is necessary for the synthesis of collagen, the major protein material of the wound. Amino acids are also necessary for the synthesis of proteins involved in the immune response and thus the fighting of infections. Vitamins and minerals are also important as co-factors in collagen synthesis these include vitamin C, vitamin A, iron, copper and zinc. In practice, vitamin C deficiency has been clearly linked with impaired wound healing.

When a sever wound has arisen as a result of major trauma, the nutritional requirements above, may be complicated by pronounced metabolic disturbances which result in losses of fat, protein and important ions. In such 'hypercatabolic' patients, requirements for all nutrients are greatly increased.
Energy and protein requirements for 65kg adult
under various clinical conditions:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Energy (Kcals/day)</th>
<th>Protein (g/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-operative</td>
<td>1500</td>
<td>65</td>
</tr>
<tr>
<td>Multiple fractures</td>
<td>2000</td>
<td>95</td>
</tr>
<tr>
<td>Sepsis</td>
<td>2400</td>
<td>110</td>
</tr>
<tr>
<td>60% burn</td>
<td>3000</td>
<td>165</td>
</tr>
</tbody>
</table>

Nutrition and the elderly orthopaedic patient

After bones reach maturity in length, they may continue to become thicker and stronger. However, in early middle age the skeleton begins to atrophy and this continues throughout the remainder of life. Decalcification of the bone is a physiological progress of ageing and is influenced by a number of factors. If this decalcification is rapid, osteoporosis may result, a condition especially prevalent in post menopausal women, when the lack of oestrogens and immobility are largely responsible. Thus, many elderly women admitted to hospital with fractures may have fragile bones, with a matrix of reduced density. In such patients it is particularly important that tissue and bone repair are strong and secure, and that nutritional status is adequate on leaving hospital. Calcium and vitamin D are required for the formation of strong, new bone as well as protein and energy.

Conclusion

Elderly patients admitted for surgery are a particularly nutritionally vulnerable group. Not only are they at risk of being malnourished on admission to hospital, but they are likely to be unable to meet the nutritional demands of recovery from surgery. This can result in poor wound healing, increased tendency to infection, and so prolong patient suffering and increased costs. The identification of at risk patients, and the provision of adequate early nutritional support can greatly enhance patient recovery and quality of life. The nurse plays an important role in not only identifying such patients, but also in encouraging their nutrient intake and monitoring the effectiveness of a nutritional support programme.
### Appendix V

#### Nutrition and Ilona's Questionnaire - Individual Patient Score

<table>
<thead>
<tr>
<th>Q</th>
<th>Pt</th>
<th>Patients receiving NEP and Compliant to supplement</th>
<th>Patients not offered NEP and Compliant to supplement</th>
<th>Patients receiving NEP and Non-Compliant to supplement</th>
<th>Patients not offered NEP and Non-Compliant to supplement</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>21</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>22</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

xxxiv
## Appendix V

Table A6.3. Nutritional intakes of the Compliant group (including and excluding the supplement) and the Non-Compliant group, expressed for the three individual days of assessment and as the mean of the three days.

<table>
<thead>
<tr>
<th>NUTRIENT</th>
<th>DAY 1</th>
<th>DAY 2</th>
<th>DAY 3</th>
<th>MEAN OF 3 DAYS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>C(^1) (n=8)</td>
<td>C(^2) (n=8)</td>
<td>NC (n=13)</td>
<td>C(^1) (n=8)</td>
</tr>
<tr>
<td>ENERGY (kcal)</td>
<td>2217 ± 334</td>
<td>1892 ± 427</td>
<td>1285 ± 351</td>
<td>2086 ± 422</td>
</tr>
<tr>
<td>PROTEIN (g)</td>
<td>87 ± 12</td>
<td>69 ± 12</td>
<td>51 ± 13</td>
<td>68 ± 14</td>
</tr>
<tr>
<td>FAT (g)</td>
<td>110 ± 24</td>
<td>87 ± 29</td>
<td>60 ± 20</td>
<td>95 ± 26</td>
</tr>
<tr>
<td>CARBOHYDRATE (g)</td>
<td>229 ± 82</td>
<td>167 ± 60</td>
<td>144 ± 49</td>
<td>238 ± 62</td>
</tr>
</tbody>
</table>

Results are expressed as mean values (±sd), where n refers to the number of values.

C\(^1\) refers to the nutrient intake of the Compliant group, including the supplements.

C\(^2\) refers to the nutrient intake of the Compliant group, excluding the supplements.

NC refers to the nutrient intake of the Non-Compliant group.
Table A5.4

Nutritional intakes of the group receiving the Nutrition Education Programme (excluding the supplement) and the group who were not offered the Nutrition Education Programme, expressed for the three individual days of assessment and as the mean of the three-days.

<table>
<thead>
<tr>
<th>NUTRIENT</th>
<th>DAY 1</th>
<th>DAY 2</th>
<th>DAY 3</th>
<th>MEAN OF THREE DAYS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Received NEP (n=11)</td>
<td>Not offered NEP (n=10)</td>
<td>Received NEP (n=11)</td>
<td>Not offered NEP (n=10)</td>
</tr>
<tr>
<td>ENERGY (kcal)</td>
<td>1389 (+ 454)</td>
<td>1496 (+ 402)</td>
<td>1354 (+ 366)</td>
<td>1367 (+ 458)</td>
</tr>
<tr>
<td>PROTEIN (g)</td>
<td>82 (+ 17)</td>
<td>53 (+ 12)</td>
<td>61 (+ 14)</td>
<td>67 (+ 8)</td>
</tr>
<tr>
<td>FAT (g)</td>
<td>66 (+ 30)</td>
<td>76 (+ 22)</td>
<td>69 (+ 22)</td>
<td>54 (+ 25)</td>
</tr>
<tr>
<td>CARBOHYDRATE (g)</td>
<td>145 (+ 54)</td>
<td>161 (+ 54)</td>
<td>139 (+ 43)</td>
<td>163 (+ 61)</td>
</tr>
</tbody>
</table>

Results are expressed as mean values (+ sd), where n refers to the number of values.