Chapter Three: Methods

3.1 Study design

This study was a non-experimental retrospective evaluation of patient outcomes in the ‘Your Choice’ weight management programme provided by the community nutrition service of South Manchester PCT, which was ongoing at the time of data collection. This study used triangulation methods to evaluate the programme. It included a retrospective analysis of data previously obtained longitudinally from participant health assessments over the previous two years. This allowed a relatively large sample and avoided the financial and time costs of collecting primary data prospectively. This was followed by a retrospective cross-sectional questionnaire, which was an objective method to assess participant satisfaction and collect information on changes participants made to their lifestyles after attending the education day.

3.2 Population and participants

This study used a convenience sampling technique to identify subjects that met the inclusion criteria. All overweight and obese male and female adults who attended the education day as part of the ‘Your Choice’ weight management programme and agreed to take part in the study were included. Participants were eligible to attend the programme provided they were: over 18 years of age; living within the area served by South Manchester PCT; referred by a health professional or self-referred; and had an initial individual dietetic consultation to inform them of the programme and ensure they were suitable to take part. Criteria for exclusion from the data analysis phase were: individuals that did not attend the education day; did not attend at least one follow-up appointment; had a BMI less than 25kg/m²; or those for which data was
unavailable. Individuals were excluded from the questionnaire phase if they: did not attend the education day; were included in the pilot questionnaire; had no recorded address; did not return the questionnaire within the specified time or did not agree to take part in the questionnaire. None of the participants included in the study had previously attended the ‘Your Choice’ programme. Participants included those treated with weight management medications (Orlistat and Sibutramine) and those with other medical conditions, such as hypertension and type 2 diabetes.

Participants on the programme represented a selected group. They selected themselves by attending their health professional or approaching the ‘Your Choice’ team directly, agreeing to take part and attending the ‘Your Choice’ education day. They had also been selected by their health professional as suitable for referral.

A computerised departmental database was used to generate a list of participants enrolled on the programme since its initiation in February 2005. All patients eligible for the study were selected from this list according to the defined inclusion and exclusion criteria. There was no need to extract a random sample from the population because the population studied was manageable in terms of financial and time limitations.

3.3 Intervention- the “Your Choice” programme

This study was based in the Community Nutrition Service department at Withington Community Hospital in South Manchester PCT. “Your Choice” is a dietitian-led lifestyle-modification weight management programme. Patients can enter the programme via referral by a health professional or self-referral. Each patient attends
an initial appointment with the dietitian to inform them about the programme and ensure they meet inclusion criteria for the programme.

The programme aims to provide patients with knowledge, skills and support to help them to control their weight. The education day involves about 10 participants. Previously, patients referred to the community nutrition department received individual appointments but waiting lists were long and it was difficult to offer consistent follow-ups due to time limitations. The group education day allows more individuals access to a dietitian for a longer period of time with a shorter waiting list and it is a cost effective way of addressing patient numbers. This enables detailed education, support and encouragement to be provided to individuals.

The education day focuses on nutrition education, behavioural techniques and physical activity. Topics covered include the Eatwell Plate, reducing calories, portion size and food labelling. Behavioural techniques include goal setting, self-monitoring and stimulus control. Patients participate in practical activities including completing food diaries, tasting regular and reduced fat foods and discussing food labels. The day includes practical demonstrations on the nutritional content of fresh and convenience meals and actual versus recommended portion sizes. Physical activity is discussed, including the recommended frequency, intensity, time and type, benefits of exercise and common barriers to exercise. Written leaflets are provided to reinforce verbal information. All advice is tailored to the local population and to local shopping and leisure facilities. Participants are also offered the opportunity to attend the South Manchester Improving Lives Through Exercise (SMILE) programme, to help increase physical activity levels. Participants receive a baseline health assessment, and are
offered individual three-monthly health assessments to monitor their progress. Participants also have the opportunity to attend an additional individual appointment with a dietitian for further support. Additional services provided by the department include cookery sessions and walking or cycling groups that patients can attend. Progress reports are sent to the referrer and GP after each follow-up appointment.

3.4 Measurements

3.4.1 Independent and dependent variables

In this study, the independent variable was the “Your Choice” education day and subsequent follow-up health assessments. The dependent variables included weight (kilograms), BMI (kg/m²), body fat (%), blood pressure (mmHg) and heart rate (beats per minute), reported nutritional knowledge, food choices, activity levels, self-efficacy and quality of life. Data relating to changes in weight, BMI, blood pressure, body fat and heart rate was extracted and analysed to identify any significant changes in these parameters while individuals were participating in the programme. Other baseline data collected included gender (male/female), age (years) and number of follow-up health assessments attended. This helped provide a more comprehensive representation of patient characteristics at baseline.

All measurements were recorded by trained nutrition assistants using standardised methods. Weight was measured to the nearest 0.1kg using a Marsden MPMS200 professional digital medical scale (*Marsden Weighing Group UK Ltd.*), which had a capacity of 200kg x 0.1kg, with 100g graduations and was under an annual maintenance contract. Participants were measured in light clothing without shoes. Height was measured in meters using a freestanding height measure (Seka,
Body mass index was calculated using the formula weight (kg)/height\(^2\) (Garrow and Webster, 1985). Blood pressure and heart rate were measured using an Omron MX 3 automatic blood pressure monitor (Omron Healthcare UK Ltd). The measurement range was 0-280mmHg with an accuracy of ±3mmHg or 2%. The heart rate measurement range was 40 to 200 beats per minute and accuracy was ±5bpm. Body fat percentage was measured using an Omron BF300 body fat monitor (Omron Healthcare UK Ltd), which had a range of 4.0% to 50.0% and accuracy of 4.1% and had been validated as an accurate measure (Moreno et al., 2001).

### 3.4.2 Participant questionnaire

Due to time and financial limitations and the retrospective design of this study, it was necessary to evaluate patients’ reported changes in nutritional knowledge, food choices, physical activity, self-efficacy and quality of life by cross-sectional questionnaire, rather than measure actual changes. Questionnaires are a popular, cost-effective means of obtaining objective information on knowledge, beliefs, attitudes and behaviours from participants over a wide geographical area (Sim and Wright, 2000; Wall et al., 2002; Boynton & Greenhalgh, 2004). A review of the literature was conducted to investigate validated questionnaires for weight management programmes, however no such tools were identified.

The aims of the questionnaire were to assess participant satisfaction with the education day and subsequent follow-up appointments; identify reported changes in participants’ nutritional knowledge, food choices and physical activity; assess participants’ self-efficacy at managing their weight and changing their lifestyle.
following the education day; and assess participants’ quality of life since attending the education day. It also aimed to establish the proportion of participants who did not attend follow-up appointments and identify possible reasons for this. Participants were also given the opportunity to provide comments on the programme.

A self-developed questionnaire was most appropriate to address the research questions of this study, as it needed to be specific to the structure and content of the “Your Choice” programme. Appendix 4 provides details of the development of the questionnaire used in this study. Questions were adapted from previous questionnaires evaluating weight management programmes (Keppie and Lyon, 1999, Read et al., 2004), diabetes management programmes (Paddock et al., 2000, Toobert et al., 2000), and the questionnaire currently used to evaluate the “Your Choice” education day. The lead investigator attended the education day to observe the content and structure of the session and carried out semi-structured interviews to identify likely responses to questions. Results of the semi-structured interviews are presented in Appendix 3.

Studies have consistently shown that low response rates are often due to participants being unable to read or follow the questionnaire (Boynton & Greenhalgh, 2004). Therefore, it is recommended to pilot questionnaires on participants who are representative of the sample (Boynton & Greenhalgh, 2004). Piloting tests the data collection tool on a small sample to ensure it is effective (Payne, 1999) and provides feedback about the wording and clarity of questions, appropriateness of the questions for the target population, and the presence of redundant or unnecessary items (Wall et al., 2002). The pilot questionnaire was administered via post to ten participants that had attended the ‘Your Choice’ education day. The feedback was used in the
development of the final questionnaire (Appendix 6). The pilot questionnaire and results are presented in Appendix 5.

The questionnaires were administered via post to all eligible participants in the study. Each questionnaire included a personalised introductory letter from the Community Nutrition Service, participant information sheet, instructions for completing the questionnaire and a stamped, addressed return envelope (Appendix 6). Participants were asked to complete the questionnaire and return it to the lead investigator within two weeks; those that did not respond within this timeframe were sent a reminder letter and questionnaire.

Participant satisfaction was evaluated by asking participants how they rated waiting times for the education day, the location of the education day, the programme staff, the group setting, the measurements taken at the education day, the information given and overall satisfaction. Satisfaction with follow-up appointments was addressed by investigating possible reasons for non-attendance. Participants who did attend follow-up appointments were asked about the waiting times and the setting of appointments. In the final section of the questionnaire, participants were asked about their confidence and ability to make healthy lifestyle changes following the education day and the usefulness of follow-up appointments in maintaining changes and monitoring outcomes. Two open-ended questions at the end allowed participants to give additional positive and negative comments.
3.5 Data management

Participants’ data was stored in a database system. Individuals were not identifiable by name, initial, hospital number or other distinguishing features, and were assigned an anonymous and unique study identification number to maintain their confidentiality and anonymity. Questionnaires were also allocated an identification number and information from returned questionnaire was entered onto the database corresponding to the number on the questionnaire. The study identification numbers were matched with participant details held on a separate, secure database. All data was destroyed when the study was complete.

Information collected during the course of this study was not used other than for the purpose of the study and its dissemination. All data was stored securely on the hard drive of a computer (Toshiba Sattelite A30 Series) that was username and password protected and only available to the main investigator. It was backed up by memory stick (Disco, 126 megabytes) stored securely in a locked deposit box in the researchers home. If study data was transferred between sites, it was ensured that its transport was safe and secure.

3.6 Ethical implications

This study was approved by the School Research Ethics Committee at the University of Chester (Appendix 7). All participants gave informed consent to participate in the questionnaire survey (Appendix 6). Caldicott Principles (1997), the Data Protection Act (1998) and the NHS Confidentiality Code of Practice (2003) allow for the use of patient data for the purposes of clinical audit with the view to review and improve healthcare, therefore participant consent was not required for the use of participant
data from baseline and follow-up health assessments. When ethical approval was obtained, data collection commenced.

This study was non-invasive. It did not require any additional measurements to be taken, other than what were routinely measured at follow-up health assessments as part of the programme. Participant baseline and follow-up information was collected from a computerised database. All the questions in the questionnaire were necessary to address the research objectives, the questions were clear and unambiguous to ensure participants were able to understand them and answer appropriately. This was assured by the pilot study. There was minimal risk that the questionnaire would have caused the participants to reflect negatively upon the weight loss programme and therefore jeopardise clinical outcomes.

Each participant was provided with a participant information sheet, a cover letter from the Community Nutrition Service of South Manchester PCT and instructions for completing the questionnaire (Appendix 6). The questionnaires were printed on headed paper to ensure participants were aware the study involved both South Manchester PCT and the University of Chester. The information sheet was written in non-technical terms and explained the aims and purpose of the study, with the contact name and number of the lead investigator provided. Furthermore, participation in the questionnaire was voluntary and not participating would have no negative consequences for participants.
3.7 Statistical analysis

All statistical analysis was carried out using the Statistical Package for the Social Sciences (SPSS) computer programme (*Version 14, SPSS, Chicago, Ill., USA*). Data was coded, screened and cleaned before analysis. The data collected in this study was quantitative.

3.7.1 Hypothesis and research questions

This evaluation aimed to evaluate the ‘Your Choice’ programme by testing the following null hypothesis.

Hypothesis 1: Participants’ weight, BMI, systolic and diastolic blood pressure, heart rate and body fat did not change while taking part on the ‘Your Choice’ programme.

This evaluation also aimed to answer the following research questions.

1. Did participants’ reported food choices, nutritional knowledge, physical activity self-efficacy and quality of life change as a result of taking part in the education day?

2. Were participants in the ‘Your Choice’ programme satisfied with programme (education day and follow-up health assessments) and did they have any additional comments that could improve the programme?

3. What was the proportion of patients that attended follow-up health assessments and what are the possible reasons for non-attendance of follow-up?
3.7.2 Descriptive statistics

Descriptive statistics were obtained to illustrate the characteristics of the population studied. The Kolmogorov-Smirnov test was used to assess the normality of continuous data, where a non-significant result \((P>0.05)\) indicates normality (Pallant, 2001). Data was presented as mean and standard deviation if normally distributed and median and range if not normally distributed.

Data obtained from the questionnaire was categorical nominal data and was presented as frequencies and percentages. A codebook was prepared to allow the information obtained from the questionnaire to be statistically analysed. As questionnaires were returned, they were checked to ensure they are filled out appropriately. Analysis of the baseline characteristics of responders and non-responders to the questionnaire, and attendees and non-attendees to follow-up was performed to provide information on response and attendance bias. The questionnaire contained two open-ended questions; participant responses were noted, grouped and coded according to discrete themes in order to identify any trends in the range of views regarding the programme and this data was presented as frequencies and percentages.

3.7.3 Analytical statistics

To test the null hypothesis, mean \((\pm\text{S.D.})\) weight, BMI, blood pressure, heart rate and body fat were analysed using paired \(t\)-tests to identify changes between baseline and each follow-up health assessment attended. Comparisons of mean \((\pm\text{S.D.})\) weight were also performed between baseline and each three monthly follow-up appointment. Where data was not normal, it was transformed using a square root calculation to allow parametric tests of significance to be used. A result of \(P\) less than or equal to
0.05 was deemed to be statistically significant. Independent samples $t$-tests (Mann-Whitney tests for non-normal data) were performed to assess whether the baseline characteristics of those responded to the questionnaire and those who attended follow-up appointments differed from those that did not. A one-way between groups analysis of variance was conducted to explore the impact of baseline BMI on both weight change at each follow-up appointment and total weight change, and an independent samples $t$-test was performed to explore the impact of gender on mean weight change at each follow-up appointment and total weight change.

The predicted outcome of this study was to evaluate the effectiveness of the ‘Your Choice’ programme. To be deemed effective, the programme should predominantly result in weight loss, however, if weight is maintained the intervention can also be deemed effective. Other health parameters may be improved which would also contribute to the effectiveness of the programme.