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Study protocol

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A randomised trial of an internet weight control resource: The UK Weight Control Trial [ISRCTN58621669]

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Abstract

Background: Obesity treatment is notoriously unsuccessful and one of the barriers to successful weight loss reported by patients is a lack of social support. The Internet offers a novel and fast approach to the delivery of health information, enabling 24-hour access to help and advice. However, much of the health information available on the Internet is unregulated or not written by qualified health professionals to provide unbiased information. The proposed study aims to compare a web-based weight loss package with traditional dietary treatment of obesity in participants. The project aims to deliver high quality information to the patient and to evaluate the effectiveness of this information, both in terms of weight loss outcomes and cost-effectiveness.

Methods: This study is a randomised controlled trial of a weight loss package against usual care provided within General Practice (GP) surgeries in Leeds, UK. Participants will be recruited via posters placed in participating practices. A target recruitment figure of 220 will enable 180 people to be recruited (allowing for 22% dropout). Participants agreeing to take part in the study will be randomly allocated using minimisation to either the intervention group, receiving access to the Internet site, or the usual care group. The primary outcome of the study will be the ability of the package to promote change in BMI over 6 and 12 months compared with traditional treatment. Secondary outcomes will be the ability of the Internet package to promote change in reported lifestyle behaviours. Data will be collected on participant preferences, adherence to treatment, health care use and time off work. Difference in cost between groups in provision of the intervention and the cost of the primary outcome will also be estimated.

Conclusion: A positive result from this study would enhance the repertoire of treatment approaches available for the management of obesity. A negative result would be used to inform the research agenda and contribute to redefining future strategies for tackling obesity.

Background

Obesity is a major public health problem in the UK today and one that can be socially isolating for the person concerned. The most recent figures on prevalence in the UK

are 17% for men and 21% for women, with levels continuing to rise [1]. Obesity is a risk factor for a range of health problems, most notably coronary heart disease (CHD) [2]. However obesity treatment is notoriously unsuccessful and despite the increasing prevalence of obesity, may only yet reach a small proportion of patients [3]. Barriers to successful weight loss include negative attitudes towards the obese, held by society as a whole and by health professionals who may be involved in treating obesity [4], a lack of social support [5] and use of poorly evaluated weight loss programmes [6]. Social support is often cited by patients as important in achieving weight loss and includes regular contact with health professionals and support from others attempting to lose weight. However, from the health professional's viewpoint, a lack of time and resources means that such strategies are difficult to implement.

Novel methods of supporting patients in their weight loss efforts, without significantly increasing the workload of health professionals involved in their care, are therefore needed. The use of new technology could facilitate this through telephone or email contact with a health professional and online chat rooms for peer support. However, a recent report by the consumer organisation 'Which' found that of the Internet diet sites currently available, 7 out of 10 provided a poor service [7]. One of the main criticisms made was that many of the sites reviewed did not provide personalised advice or advice by a qualified health professional. The potential therefore exists for health professionals to deliver well-evaluated, effective weight management programmes via the Internet to tackle this important public health problem.

Though limited in number, there are some strategies using new technologies that have been found to be successful in weight management. One study used a hand-held computer [8] and found it to be as effective as therapist-conducted treatment for the management of mild overweight, as well as more cost-effective. Another study used the Internet to deliver a behavioural weight loss program and found greater weight loss in participants completing this program compared with those given Internet education only [9]. However, both studies took place in the US and did not compare Internet delivery of a weight management program with usual care, which is a more meaningful comparison for the NHS in the UK. Further, they both used overweight rather than obese participants for some or all of the intervention.

The proposed study aims to compare a web-based weight management package with traditional dietary treatment of obesity in participants recruited from the Leeds area. The Internet offers a novel and fast approach to the delivery of health information. We have conducted research into the use of the Internet by health professionals and patients and have found a willingness to embrace new technologies, as long as measures are taken to ensure the accuracy and integrity of information [10]. Information on diet and health is widely available on the Internet but is often of dubious quality and both the health professionals and patients studied wanted information to be written by health professionals and bound by a code of ethics, such as Health on the Net (HON). It is also important that any information is targeted effectively and personalised for the individual if behaviour change is to occur. This project aims to deliver high quality information to the patient and to evaluate the effectiveness of this information, both in terms of weight loss outcomes and cost-effectiveness.

Aims of the study

• To develop an Internet-based interactive and personalised package for weight control (http://www.ukweightcontrol.co.uk)

• To explore acceptability of the Internet-based package to potential users

• To conduct a randomised-controlled trial on the effectiveness of the Internet-based package in promoting weight loss compared with usual care

• To promote the results through publication and dissemination via local and national health and community networks

Research question

Is the use of an Internet-based interactive, personalised package for weight control an effective method of supporting patients in weight loss attempts?

Hypothesis

An Internet-based package for weight control, alongside "usual care", is a more effective treatment for obesity than "usual care" methods alone.

Methods

Population

This study will recruit participants from within General Practice (GP) surgeries in the Leeds (UK) area. Posters will be placed in participating GP practices, advertising the study and asking interested potential participants to call the study centre or to inform their General Practitioner (GP) or practice nurse of their interest. Potential participants will then be screened for eligibility to participate.

Inclusion criteria

• BMI >30 kg/m^2

• 18–65 years of age (due to body composition changes over the age of 65 years)

• Able to access the Internet at least once per week

• Able to read and write in English (for the purposes of accessing the site and completing questionnaires)

Exclusion criteria

• Pregnant or lactating women

• Women planning on becoming pregnant within the next year

• Any illness or reason where the GP feels that the patient should not be taking part in a clinical trial.

Sample size

With 180 participants in total we should be able to detect a difference of 5 kg weight loss (approximately 5% of body weight) or less than 2.5 kg/m^2 in BMI between the two groups with 80% power. This assumes a two-sample t-test, 5% significance levels, a standard deviation for weight of 12 kg and for BMI of 5.5 kg/m^2. An additional 22% of participants will be recruited to take account of any loss to follow-up, giving a target recruitment figure of 220.

Study procedure

Eligible participants will be sent a covering letter, participant information sheet, consent form and an initial approach questionnaire. Consenting participants will be contacted by telephone to arrange a first visit with the research team at their GP surgery. At the first visit height, weight, waist and hip circumference will be measured for each participant. The baseline questionnaire will then be administered. At this point the participant will be randomly allocated using minimisation (Minim) into either the treatment group or the usual care group. Because of the nature of the intervention, it is not possible to blind either the participants or the researchers to the group assignment. Participants will be followed-up 6 months and 12 months after randomisation. At these visits they will have their height, weight, waist and hip measurements repeated, and will be asked to complete a further questionnaire at each visit.

Intervention Group

The UK weight control site will provide free weight management information based on the best possible advice from experts in the field. It will enable patients to manage their own care and to vary the frequency of use according to their own needs. The site will offer personalised advice to participants, which, in the context of the Internet, involves targeting the information provided to an individual based on their responses to a series of online questions. This will enable targeted motivational statements to be generated to participants whenever they visit the site. In addition, details of progress in terms of self-reported weight loss will be stored on the site, accessible only to the individual concerned. Participants will be given a demonstration of the website and its services, along with a username and password to access the site. They will be encouraged to log on frequently over the first few days in order to get accustomed to the site. After that participants will be encouraged to visit the site as often as they wish. Site usage will be monitored, along with the nature of participant queries and the time spent in dealing with them. Automatic emails will be generated if participants do not visit the site regularly to encourage them to visit more often.

'Usual Care' Group

Participants randomised to this group will be advised to continue with their usual approach to weight loss, e.g. to contact their GP, obtain a dietetic referral, or visit commercial slimming clubs. Participants will be given a small amount of printed information to prevent 'resentful demoralisation'. This will be developed to reflect the type of information available both within the primary care setting and featured on the website.

Statistical methods

Data will be analysed using SPSS. Differences in the primary outcome (change in BMI) and secondary outcomes will be compared using t-tests for continuous variables and chi-squared tests for categorical variables. Where continuous variables are not normally distributed, appropriate non-parametric statistical tests will be employed.

Outcomes

The primary outcome will be the ability of the Internet package to promote change in BMI over 6 and 12 months compared with traditional treatment. Secondary outcomes will be the ability of the Internet package to promote change in reported lifestyle behaviours compared with traditional treatment. In addition, data will be collected on participant preferences, adherence to treatment, health care use and time off work. Difference in cost between groups in provision of the intervention and the cost of the primary outcome will also be estimated. The outcome of the trial will be known in April 2005.

Confidentiality and anonymity

Participants will be identified through the use of an identification number only. No possible identifiers will appear on any publicly accessible documentation. Data will be stored in locked filing cabinets and contact details will be stored separately to identification numbers.

Relevance to clinical practice

A positive result would enhance the repertoire of treatment approaches available for the management of obesity. A negative result would be used to inform the research agenda and contribute to redefining future strategies for tackling obesity.

Competing interests

None declared

Authors' contributions

The Nutrition Epidemiology Group, at the Nuffield Institute for Health, University of Leeds, is responsible for co-ordinating the trial, in collaboration with the School of Healthcare Studies, the University of Leeds.

SK is the Principal Investigator, who conceived of the idea and obtained funding for the study. EH is a co-applicant on the grant and provides advice and guidance on the study design and conduct of the RCT. AM is co-ordinating the day-to-day running of the study. JP was the initial research manager on the project, who put together the content of the site and now advises on the web site content. DG is the statistician on the study. JT is the database manager and web designer/web master. All authors have contributed to the set up and design of the study. JR is an advisor on the study on aspects relating to project management.

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