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A randomised feasibility trial of a new lifestyle referral assessment versus usual assessment in an acute cardiology setting

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Abstract

Background—A healthy diet, taking exercise and not smoking or consuming alcohol in excess are important to reduce the risk of cardiovascular disease either alone or in combination with statin medication. Health education, including providing information to patients on healthy living and guidance on how to achieve it, is a key nursing function.

Objectives—This study aims firstly to assess the feasibility of conducting a full-scale trial of lifestyle referral assessment as shown by recruitment rate, data collection and follow-up; and secondly to assess proof of concept and explore possible mechanisms of change.

Methods—A single-centre, randomised two-arm parallel-group, unblinded feasibility trial conducted in an acute teaching hospital trust. Participants followed up at 3 and 6 months post-randomisation.

Results—887 patients screened for eligibility of whom 132 (15%) were randomised into the trial. Of the patients allocated to the individualised assessment: 27% accepted referral or self-referred by 3 months in comparison to 5% allocated to the usual assessment.

Conclusions—We demonstrated that a full-scale trial is feasible, and that an individualised approach increased the number of patients accepting referral to a formal programme and initiating

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lifestyle change. However, we should consider the aim of the assessment and ways in which the process of change can be optimised in order to produce long-term benefit for patients.

Trial registration: Current Controlled Trials ISRCTN41781196.

Keywords

Randomised controlled trial; cardiovascular risk factors; lifestyle and behaviour change

Introduction

The global burden of cardiovascular disease (CVD) and its risk factors are well documented. Some risk factors for CVD cannot be modified but some can be controlled by medication or modified by lifestyle change.[1,2] Health education, including providing information to patients on healthy living and guidance on how to achieve it, is a key nursing function.

To make a difference to health, lifestyle change has not only to be initiated but also maintained. Psychological theories like the Transtheoretical model [3] and the Theory of Planned Behaviour [4] attempt to explain the process of change but assume a degree of persistence. In reality people tend to dip in and out of lifestyle change; dieting or increasing physical activity, for example, in preparation for a summer holiday or special event. Interventions based on theoretical models of this type need to take this into account when implemented in real-life contexts [5].

Many studies measure outcome by uptake of lifestyle change programmes but there is a difference between taking up a lifestyle change programme and the initiation of actual change. In previous work we reviewed the evidence to identify the main influences on lifestyle change and identified five key factors that affect uptake and continued participation in lifestyle change programmes: (i) beliefs about the need to change; (ii) knowledge about lifestyles; (iii) support from family and friends; (iv) emotional state and (v) problems with finance and travel.[6]

Following the Marmot Report [7], the UK Department of Health introduced a raft of initiatives to improve health and wellbeing including 'Every Contact Counts' [8] which encourages nurses and other public-facing staff to engage patients conversationally about lifestyle, and give brief advice about health and lifestyle choices. However, coverage both in terms of the staff who engage patients in this way, and the topics they address, is patchy. We hypothesise that acceptance of referral and uptake of lifestyle change will have a better chance of success if a systematic approach is adopted to produce an individualised plan for change. We therefore developed a lifestyle referral assessment based on the factors that emerged from our synthesis of the evidence,[9] which aims to elicit individual difficulties in order to produce a tailored plan for lifestyle change. Our approach is compatible with the recommendations of the most recent NICE guidelines for lifestyle change [10].

In this study we test the feasibility of conducting a full scale trial of lifestyle assessment and referral by comparing our new individually tailored assessment with local usual practice. We explore acceptance of referral to a lifestyle management programme, either self-directed

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change or a formal, routinely available programme, and its effect on lifestyle change in patients with modifiable risk factors for CVD admitted to acute cardiology services with a suspected cardiac event.

Methods

Study design

The Healthy Hospital Trial (HHT) is a single-centre, randomised controlled, two-arm parallel-group, unblinded feasibility trial that was conducted on two cardiology wards at the Leeds Teaching Hospitals Trust. Its primary aim was to explore the feasibility of individualised lifestyle referral assessment, estimate the rate of recruitment, and explore the feasibility of collecting the data and follow-up of participants to inform the sample size of a definitive trial. A secondary aim was to test the concept that an individually tailored assessment improves uptake of lifestyle change compared to usual assessment. The trial protocol has been published elsewhere [11]. The trial was funded by the National Institute of Health Research Collaboration for Leadership in Applied Health Research and Care (CLAHRC) for Leeds, York and Bradford.

Recruitment

We aimed to recruit people at risk for heart disease who would not usually be referred to a cardiac rehabilitation programme. Eligibility criteria for the study were broad:

1. Patients admitted to hospital with a suspected diagnosis of acute coronary event, myocardial infarction or symptoms of a cardiac nature;
2. Male or female aged between 40 and 74 years (within the NHS Health Check age range) at the time of screening for recruitment;
3. Willing and able to give written informed consent.

We excluded patients currently receiving specialist treatment with a primary focus on alcohol, smoking, diet or exercise; those with no modifiable risk factors for vascular events; those of no-fixed abode or mainly resident abroad, or currently serving a sentence in prison or with outstanding legal issues likely to lead to imprisonment (i.e. not available for follow-up); those who were unable to take part in either intervention using spoken English or unable to self-complete the English language outcome measure tools.

The flow of patients through the trial, and exclusion categories, are shown in the CONSORT diagram (Figure 1). Demographic details of the participants are given in Table 2.

Intervention

The new individualised assessment was an add-on to the local usual assessment used by the cardiac rehabilitation nurses. The usual assessment was delivered in both arms of the trial. (See Appendix A). Both the new and usual assessments are simple checklists that include an option for referral to lifestyle change services. The new assessment differs by incorporating a discussion of barriers and facilitators based on the key factors influencing lifestyle

change [9]. It includes an option for self-directed change with support to set goals. For the purpose of the trial both new and usual assessments were delivered by one researcher.

All participants were given basic lifestyle advice and contact details for a locally-provided, online healthy living programme (Leeds Let's Change),[12] which is based on advice and support provided by the national 'Change for Life' programme developed by the UK Department of Health.[13] Requests for referrals from participants in the control arm were passed to ward staff for action.

The level of support provided in the intervention arm was more individualised. The researcher talked to the patient about their lifestyle to identify what was important to them and what they wanted to change. Patients were encouraged to identify their personal priorities for example whether to focus on one specific lifestyle factor or tackle two or more things together. Methods to effect change were discussed and an approach chosen based on individual needs and preferences: for example those choosing self-led change were encouraged to identify personal goals and use an individualised record card; those opting for a formal programme were assisted to access the Leeds Let's Change website using a laptop computer and helped to identify a suitable, local programme. Referrals were made without delay, or information was provided to permit self-enrolment after discharge.

Data collection

Participants were assessed for eligibility in hospital and provided with written information. After consent was obtained, baseline assessment of lifestyle and randomisation was carried out on the ward before discharge. We used simple randomisation with no stratification, details of which are reported elsewhere [11]. Participants were followed up three and six months after randomisation to determine self-reported changes in lifestyle. We defined ***uptake*** as acceptance of referral to a formal programme or an expression of willingness to undertake a self-led programme of change, scored as binary (Yes/No); and ***initiation*** of change as participation in a formal programme or a self-directed programme that was intended to result in change either in diet, physical activity, smoking or alcohol consumption at any time (binary). Within initiation we identified three categories of change to represent the maximum achieved change in any one of the participant's nominated lifestyle factors: (a) no change; (b) lifestyle change in progress and (c) maintenance of lifestyle change (sustained change that persisted over 10 weeks) (ordinal). In our published protocol we had proposed four categories of change but we found it difficult to distinguish between 'persisted' and 'maintained' in the qualitative follow-up interviews hence we combined persistence and maintenance of change in one category.

Validated questionnaires were administered at baseline and follow-up points. Social satisfaction was measured using the Social Satisfaction Questionnaire (SSQ) an eight-item scale scored 0 to 3, where a higher score indicates less satisfaction with the respondent's social situation [14]. Subjective wellbeing and psychological status were measured using the Clinical Outcomes in Routine Evaluation (10-item version: CORE-10) scored 0 to 4 with higher scores indicating more severe psychological distress [15]. Health-related quality of life was assessed using the European Quality of Life – 5 Dimensions (EQ-5D), a generic measure of health status where health is characterised on five dimensions (mobility, self-

care, ability to undertake usual activities, pain, anxiety or depression) and a visual analogue scale[16]. We collected data on psycho-social elements because our review of the evidence showed that factors like beliefs, family support, finances and transport affected uptake and participation in lifestyle change. We thus considered these factors relevant to an individualised referral assessment, and tested our assumptions as part of the proof of concept study.

Follow-up was conducted by interview over the telephone and only occasionally in patients' homes or at the research office. We assessed self-reported participation in lifestyle change interventions using the outcome in which most change had been identified for the component domains (i.e. alcohol, smoking, dieting and physical activity). As part of usual care, participants in both arms could opt for a lifestyle referral at any time. In these cases, trial participants were reminded about the 'Leeds Lets Change' website and advised to contact their GP or practice nurse for further advice.

Data analysis

Feasibility of recruitment, data collection, the intervention and follow-up were assessed qualitatively, supported by descriptive statistics summarised primarily in a CONSORT diagram. Proof of concept analyses were conducted once at the end of the trial on an intention-to-treat basis. We used SAS software and focused on confidence interval estimation, in accordance with a pre-specified statistical analysis plan. Missing data were assumed to be missing completely at random (MCAR) with only complete-cases used in the analyses. Adjusted and unadjusted odds ratios, with 95% CIs, were calculated for each component of successful uptake of lifestyle advice using exact logistic regression for binary outcomes, proportional odds ordinal logistic regression for ordinal ones. Participation was further summarised by primary lifestyle factor. Drawing on these analyses, it would be feasible to proceed to a large scale evaluation, modifying the protocol, based on acceptable: (i) recruitment rates, (ii) retention rates, (iii) levels of missing data, (iv) a representative sample, (v) effective trial and treatment procedures and (vi) proof of concept.

Ethical approval

All patients gave written informed consent and the study was approved by the committee of the National Research Ethics Service for Yorkshire and the Humber (Leeds East) on 12 March 2012. Reference Number: 12/YH/0086.

Trial registration

Current Controlled Trials ISRCTN41781196.

Results

Feasibility outcomes

In total 887 patients (M:F 53%:47%) were screened for eligibility over the 4-month recruitment period and 132 (15%) were randomised at a rate of approximately 33 per month.

Participants in the two arms of the trial were similar in terms of age, gender, ethnicity and other baseline characteristics (see Table 2)

We asked participants about their preferred method of follow-up. Post and phone was preferred at baseline and at 3 months. Home visits were preferred by 21% of respondents but resources did not permit this option to be offered routinely. Of those who responded at 3 months, roughly 60% responded to the initial attempt to follow-up, 25% to the second attempt and 15% to further attempts. At 6 months, roughly 40% responded to the initial attempt, 35% to the second attempt and 25% to further attempts. Increased researcher input was needed to achieve the response rates at 6 months. Active withdrawal of consent to follow-up was minimal (4%) and only 2 deaths occurred during the trial; the two major factors causing loss to follow-up were (a) non-return of postal questionnaires and (b) being unable to contact participants by telephone. At 3 months, loss to follow-up was 15% in those allocated to the new assessment and 12% in those allocated to the usual assessment. At 6 months, this was 17% and 18% respectively. Questionnaires were missing in 38% of those allocated to the new assessment and 39% of those allocated usual assessment at 3 months, and 23% and 24% at 6 months. Questionnaire data was improved at six months by the introduction of telephone data collection.

Missing item data for CORE-10, SSQ and EQ-5D were minimal. We explored the predictors of missing questionnaire data at 3 and 6 months as part of the feasibility analysis. We found some indication that treatment arm, gender, ethnicity, education, employment, living circumstances and having a hobby all predicted missing outcomes at 3 months. Those with missing 3 month outcomes also had higher baseline CORE-10 scores. Non-white British men and participants living alone, less educated and not employed were less likely to have missing data. Treatment arm and gender were not predictive of missing outcome data at 6 months. Those with missing 6 month outcomes were more likely to smoke, drink, diet and exercise at baseline. They also had higher CORE-10 and SSQ scores at baseline and lower quality of life as measured by the EQ-5D thermometer.

All 132 (15%) patients (M:F 61%:39%; mean age 59 years; SD 15) randomised received the usual assessment; and 62 patients out of 66 in the intervention arm received the individualised assessment as intended. In one case this was due to a misunderstood allocation; the reasons why the remaining three did not receive the new assessment are unknown.

Proof of concept analysis

Tables 3 and 4 show the descriptive and inferential statistics relating to the proof of concept. Of the patients in the individualised assessment arm, 27% accepted referral or self-referred by 3 months in comparison to 5% of those allocated to the usual assessment. By 6 months, percentages were similar (23% and 4% respectively) suggesting a favourable effect on uptake for the intervention that was maintained over time in our sample (since simple randomisation was used, the unadjusted odds ratio is primary, at 6.52 [95% CI 1.66 to 37.82] at 3 months and 7.20 [95% CI 1.48 to 69.84] at 6 months). Confidence intervals are wide, reflecting the preliminary nature of these findings.

Rates of initiation of lifestyle change also favoured the individualised assessment arm but less clearly. At 3 months, 75% of the individualised assessment arm and 68% of the usual assessment arm had initiated changes in their lifestyle (unadjusted odds ratio 1.38 [95% CI 0.55 to 3.52]). At 6 months, the percentages were 85% and 75%, suggesting increased initiation of change over time in both arms, with the gap widening slightly (unadjusted odds ratio 1.86 [95% CI 0.64 to 5.77]).

For self-reported participation in lifestyle change, 73% of the individualised assessment arm had only initiated, and 2% initiated and maintained change at 3 months compared to 65% and 2% of those allocated to the usual assessment (unadjusted odds ratio 0.68 [95% CI 0.30 to 1.53]). At 6 months, these percentages were 36% and 53% for the individualised assessment arm and 21% and 56% in the usual assessment arm (unadjusted odds ratio 0.46 [95% CI 0.22 to 0.98]). As such, more patients had initiated change in the individualised assessment arm at 6 months but no more had maintained this change. Wide confidence intervals again point to the degree of uncertainty around this conclusion.

Mechanisms

No association was found between quality of life (EQ-5D), psychological status (CORE-10) or social satisfaction at baseline and 3 months and uptake of referral at 3 months.

Discussion

Lifestyle plays a role in reducing the risk of CVD but changes in diet, increasing exercise, quitting smoking or drinking less alcohol can be difficult to achieve, even in response to a major health event.[17] The challenge of encouraging patients to follow recommendations for lifestyle change is usually tackled by nurses in primary or secondary care either with routine advice or by referral to a specific intervention. The evidence for the effectiveness of multiple risk factor interventions for primary prevention is not conclusive: randomised trials have shown some reduction in risk factors [18,19] but a Cochrane systematic review, updated in 2011, concluded they had no impact on mortality.[20] This lack of consensus is not surprising given that lifestyle interventions are complex and their components vary, patients are heterogeneous and achieving meaningful change across multiple factors is inherently difficult.

The first step on the path to lifestyle change is the uptake of advice or referral to an appropriate intervention. Checklists are useful tools for the coordination of this process and over the last few years many versions of lifestyle assessment tools and checklists have been developed. A Google search using the search term “Lifestyle referral assessment checklist” yields over 12m results. Notwithstanding the proliferation of assessment tools, there is little evidence underpinning their format or assessing their effectiveness. This is an important gap to close because referral rates reported in studies of routine practice are low.[21]. If simple and effective methods of initiating referrals can be developed, prevention of vascular events might be improved.

The feasibility study

Our trial was designed to assess the feasibility of a full-scale trial of lifestyle referrals. Recruitment targets and a retention rate of 75% at six months were met; and recruitment targets could easily have been increased if research resources had permitted more people to be approached before they were discharged. The missing data target of less than 25% at six months was also met; and contrary to usual research experience, we found non-white British men and participants living alone, less educated and not employed were less likely to have missing data. However, in common with many research studies, minority ethnic representation was low in our sample and fewer participants were randomised from more socially deprived areas.[22]. We improved our follow-up rates at 6 months by introducing telephone interviews to collect questionnaire data if postal attempts failed. A dual approach to the collection of follow-up data would therefore be recommended in a full scale trial.

We originally conceived the trial to test an intervention that could be relevant to both primary and secondary care settings and therefore opted to match the NHS Health Checks age range in our hospital sample. However, the participants' profile and high number of exclusions based on age argue against an upper age limit in secondary care.

We reviewed the trial procedures and subject to the issues identified in recruitment and the collection of follow-up data, found them suitable for delivering the intervention and conducting assessments. In our study the intervention was delivered by a researcher; roll-out to a full-scale trial would require a further assessment of the acceptability to ward staff of using the new, individualised assessment on a routine basis.

Proof of concept

The feasibility trial produced some interesting but preliminary findings in the proof of concept analysis. Most patients admitted to hospital with a diagnosed cardiac event are referred to cardiac rehabilitation programmes but the participants in this study were not because they had no confirmed cardiac diagnosis. All participants had at least one risk factor for CVD and many expressed concerns about their weight. Introduction of an individualised lifestyle assessment with a built-in referral mechanism could be a useful intervention in this group of patients, many of whom are likely to benefit from lifestyle change but are not eligible for mainstream rehabilitation. The Exercise Evaluation Randomised Trial (EXERT), for example, found that referral for tailored advice, supported by written materials, including details of locally available facilities, supplemented by detailed assessments was effective in increasing physical activity.[23]

When we compared the individualised assessment with the usual assessment we found that referrals to lifestyle change programmes or a self-managed programme of change and the initiation of change appear to be increased by our individualised approach. However, we found no association between the measures of mood and uptake of referral and lifestyle change although there was some indication that participants were more likely to accept referral and attempt lifestyle change if they scored higher for mood symptoms on CORE-10. This is an interesting observation because the evidence from our review identified mood disturbance as a barrier to lifestyle change not a facilitator [9]. This dissonance may arise from

small sample size or the trial intervention. Participants may have been unsettled by their hospital event and were therefore more likely to try and address the factors that contributed to their admission.

By six months there was no difference between participants in the arms in terms of sustained lifestyle change.

Current theory does not deal adequately with the complexities of maintaining change so interventions based upon them may not be successful [5]. We need to design interventions that work in the context of peoples' lives, and that overcome the barriers to the maintenance of change longer term. For example, instigating organisational change to raise the issue of lifestyle change with patients in non-contingent appointments and offer advice is one approach but advice alone is not enough. A recent randomised trial showed that enduring lifestyle change was unlikely after a single routine consultation even with a clinician trained in lifestyle counselling without additional intervention.[24] A full scale trial should consider the collection and analysis of longitudinal data from the lifestyle-change programmes that are accessed to track newly-referred patients prospectively through the lifestyle change process. An evaluation of the effectiveness of interventions would provide further evidence to inform future approaches.

Advice and interventions also need to be backed up by sustained programmes of support but this is clearly difficult to achieve in healthcare systems where resources are limited and the evidence for effective methods to maintain lifestyle change is lacking. Our synthesis of qualitative evidence showed that maintenance of change is, by and large, affected by the same factors that influence uptake and participation in lifestyle change programmes.[25] If these factors are addressed at an early stage and patients referred to appropriate lifestyle change interventions, there may be a better chance of change being maintained longer-term. This hypothesis was not supported by the findings of this feasibility study and would need to be tested in a full scale trial.

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Limitations of the study

The original study design proposed that a researcher would recruit and randomise patients and collect data whereas lifestyle assessment and referrals would be conducted by ward staff. This proved difficult to implement and in the final study protocol (as approved by the ethics committee) all assessments were to be conducted by a researcher. Consequently we were unable to evaluate the feasibility of introducing the new assessment as part of routine practice in the event of a full scale trial.

In practice the group of patients for which this study was designed often have very short stays in hospital and some are discharged before they receive any advice about lifestyle. It was a condition of ethical approval that patients in the usual assessment arm should be given a Leeds Let's Change contact card to ensure they were not disadvantaged by participating in the study. We therefore defined 'usual assessment' as brief lifestyle advice plus the contact card. This is a limitation of the study but its effect would be to reduce the difference between the assessments, nevertheless the proof of concept study showed that the new assessment

improved uptake of referrals or lifestyle advice compared to the standardised usual assessment.

There was a some loss to follow-up at 3-mths using postal questionnaire data collection. This was addressed at the 6-mth follow-up point by using the telephone interview to complete the questionnaires with patients if they were willing to do so. It proved to be a more reliable method, not only reducing loss to follow-up but also reducing missing data compared to the questionnaires returned by post. We would therefore recommend that either telephone follow-up or face-to-face interviews should be included in the design of a full scale trial.

Finally, we acknowledge that self-reported outcomes are prone to bias and inaccuracy but this study was designed to allow participants to choose the method of lifestyle change they preferred including self-managed lifestyle change. In practice therefore, outcomes would be difficult to monitor and the resources required to track uptake and attendance at a wide range of lifestyle interventions would be prohibitive.

Conclusions

This feasibility trial shows that before embarking on a full-scale trial we need to consider two things: firstly the implications of an assessment tool and its aims and acceptability in routine practice; and secondly how the process of change can be optimised in order to produce long-term benefit for patients. The public health benefits of success are obvious but we need to ensure that health policy and the systems that support its delivery work closely together to find methods that will have a positive impact on our health system [26].

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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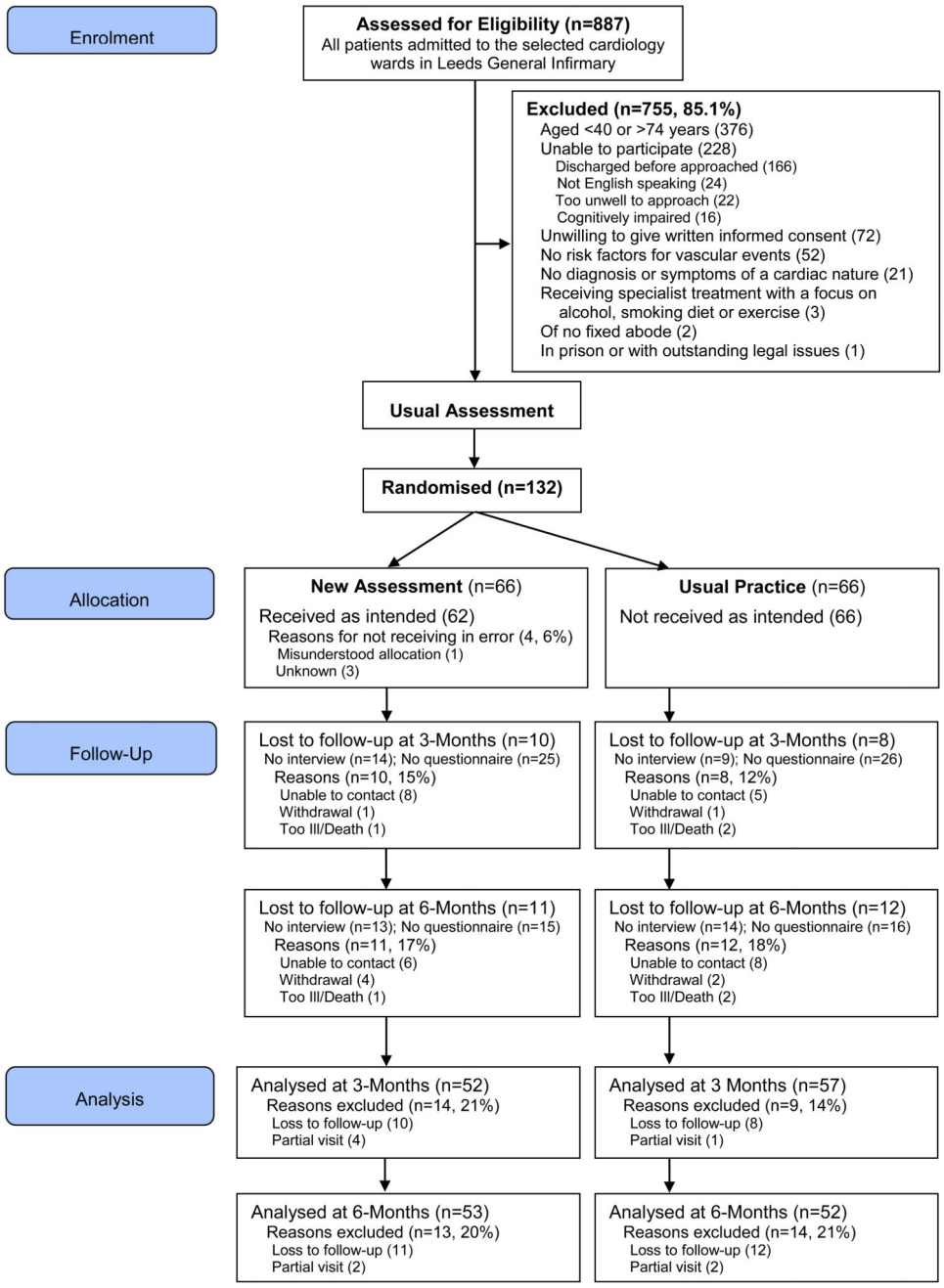

Figure 1.

CONSORT Diagram for the Healthy Hospital Trial

Footnote: There was no statistically significant difference across arms in the proportion of participants included in the analysis at 3 months (χ^2=1.32, df = 1, p=0.251).

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Table 1

What's New?

•	A lifestyle referral assessment that identifies individual barriers in order to produce a tailored plan for lifestyle change.
•	Referrals to lifestyle change programmes or a self-managed programme of change and the initiation of change are improved using an individualised approach.
•	Advice needs to be backed up by sustained programmes of support to maintain lifestyle change.

Table 2

Characteristics of the randomised participants in the Healthy Hospitals Trial

	New Assessment (n=66)	Usual Practice (n=66)	Overall (n=132)
Demographic data			
Age (years)$	59.0 (13.00) n=66	60.0 (16.00) n=66	59.0 (15.00) n=132
Female	24 (36.9) n=65	27 (41.5) n=65	51 (39.2) n=130
White	62 (95.4) n=65	59 (90.8) n=65	121 (93.1) n=130
Education to 18 yrs or above	27 (41.5) n=65	20 (30.8) n=65	47 (36.2) n=130
Employed	23 (35.4) n=65	19 (29.2) n=65	42 (32.3) n=130
Height (cm)	170.2 (11.51) n=64	168.9 (9.54) n=65	169.5 (10.54) n=129
Weight (kg)	87.4 (20.68) n=61	82.9 (16.15) n=64	85.1 (18.56) n=125
Body Mass Index (BMI)	29.8 (5.69) n=61	29.0 (5.62) n=64	29.4 (5.65) n=125
Up to 24.9 **	11 (18.0) n=61	14 (21.9) n=64	25 (20.0) n=125
25.0 to 29.9	22 (36.1) n=61	26 (40.6) n=64	48 (38.4) n=125
30.0+	28 (45.9) n=61	24 (37.5) n=64	52 (41.6) n=125
Married/Cohabiting	39 (60.0) n=65	38 (58.5) n=65	77 (59.2) n=130
Lives alone	19 (29.7) n=64	19 (29.2) n=65	38 (29.5) n=129
Socially isolated	10 (15.6) n=64	11 (17.2) n=64	21 (16.4) n=128
Number of family/friend contacts in last 28 days$	12.0 (14.00) n=46	10.0 (13.00) n=56	10.0 (14.00) n=102
0 to 7	17 (37.0) n=46	17 (30.4) n=56	34 (33.3) n=102
8 to 14	9 (19.6) n=46	15 (26.8) n=56	24 (23.5) n=102
15+	20 (43.5) n=46	24 (42.9) n=56	44 (43.1) n=102
Actively involved in interests or hobbies	41 (63.1) n=65	36 (55.4) n=65	77 (59.2) n=130
Holds a driving licence	47 (72.3) n=65	40 (61.2) n=65	87 (66.9) n=130
Drives a vehicle	43 (66.2) n=65	35 (53.9) n=65	78 (60.0) n=130
Lifestyle data (recorded over the last 28 days) *			
Smokes	19 (29.2) n=65	22 (33.9) n=65	41 (31.5) n=130
Number/week$	140.0 (70.00) n=7	40.0 (108.75) n=11	87.5 (105.00) n=18
Drinks	42 (64.6) n=65	47 (73.4) n=64	89 (69.0) n=129
Units/week$	25.0 (24.00) n=23	9.0 (33.75) n=24	15.0 (33.50) n=47
Diets	14 (22.2) n=63	10 (15.4) n=65	24 (18.8) n=128
Days/week$	7.0 (1.25) n=11	6.5 (2.00) n=5	7.0 (1.62) n=16
Exercises	24 (38.1) n=63	19 (29.2) n=65	43 (33.6) n=128
Days/week$	4.5 (5.75) n=12	2.4 (4.50) n=8	3.5 (5.75) n=20
Medication data			
Medications:			
Statins	24 (54.6) n=44	33 (75.0) n=44	57 (64.8) n=88
Beta-blockers	21 (50.0) n=42	26 (57.8) n=45	47 (54.0) n=87
Other Hypertension meds	28 (65.1) n=43	35 (77.8) n=45	63 (71.6) n=88
Antidepressants	13 (28.9) n=45	10 (22.2) n=45	23 (25.6) n=90

	New Assessment (n=66)	Usual Practice (n=66)	Overall (n=132)
Other	39 (86.7) n=45	43 (93.5) n=46	82 (90.1) n=91
Self-reported adherence: Always take as prescribed	44 (78.6) n=56	47 (85.5) n=55	91 (82.0) n=111
Questionnaire data			
AUDIT-C score	4.3 (4.10) n=64	4.5 (3.97) n=66	4.4 (4.02) n=130
CORE-10 clinical score$^	9.5 (10.50) n=64	10.0 (9.00) n=62	10.0 (10.00) n=126
0-10 Non-clinical	36 (56.3) n=64	33 (53.2) n=62	69 (54.8) n=126
11-14 Mild	8 (12.5) n=64	10 (16.1) n=62	18 (14.3) n=126
15-19 Moderate	10 (15.6) n=64	11 (17.7) n=62	21 (16.7) n=126
20-24 Moderate to severe	6 (9.4) n=64	3 (4.8) n=62	9 (7.1) n=126
25+ Severe	4 (6.3) n=64	5 (8.1) n=62	9 (7.1) n=126
SSQ mean score$&	20.0 (7.00) n=65	21.0 (4.00) n=65	21.0 (6.00) n=130
EQ-5D index score$%	0.7 (0.28) n=65	0.7 (0.54) n=63	0.7 (0.28) n=128
EQ-5D thermometer score£	52.6 (22.30) n=65	54.0 (22.09) n=65	53.3 (22.12) n=130

Data are mean (SD) n, n(%), or median (IQR) n (Note: the latter are indicated with $).

** There are 2 patients with BMIs less than 19, one in each arm;

* Number, units and days given only for those smoking, drinking, dieting and exercising respectively;

^ Potential range of scores=0 to 40, high=more severe;

& Potential range of scores=8 to 32, high=more satisfied;

% Potential range of scores=−0.59 to 1, high=better QoL;

£ Potential range of scores=0 to 100, high=better QoL

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Table 3

Uptake of lifestyle referral by 3 and 6 months

	3 Months			6 Months		
	New Assessment	**Usual Practice**	**Overall**	**New Assessment**	**Usual Practice**	**Overall**
Uptake	14 (26.9%)	3 (5.3%)	17 (15.6%)	12 (22.6%)	2 (3.8%)	14 (13.3%)
Initiation	39 (75.0%)	39 (68.4%)	78 (71.6%)	45 (84.9%)	39 (75.0%)	84 (80.0%)
Maximum Achieved Change (Overall)						
No change	13 (25.0%)	19 (33.3%)	32 (29.4%)	6 (11.3%)	12 (23.1%)	18 (17.1%)
Initiated	38 (73.1%)	37 (64.9%)	75 (68.8%)	19 (35.8%)	11 (21.2%)	30 (28.6%)
Maintained	1 (1.9%)	1 (1.8%)	2 (1.8%)	28 (52.8%)	29 (55.8%)	57 (54.3%)
Maximum Achieved Change (Alcohol)						
N/A	30 (57.7%)	31 (54.4%)	61 (56.0%)	30 (56.6%)	29 (55.8%)	59 (56.2%)
No change	15 (28.8%)	16 (28.1%)	31 (28.4%)	13 (24.5%)	15 (28.8%)	28 (26.7%)
Initiated	7 (13.5%)	10 (17.5%)	17 (15.6%)	4 (7.5%)	4 (7.7%)	8 (7.6%)
Maintained	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (11.3%)	4 (7.7%)	10 (9.5%)
Maximum Achieved Change (Smoking)						
N/A	36 (69.2%)	40 (70.2%)	76 (69.7%)	36 (67.9%)	37 (71.2%)	73 (69.5%)
No change	6 (11.5%)	7 (12.3%)	13 (11.9%)	6 (11.3%)	2 (3.8%)	8 (7.6%)
Initiated	9 (17.3%)	10 (17.5%)	19 (17.4%)	3 (5.7%)	6 (11.5%)	9 (8.6%)
Maintained	1 (1.9%)	0 (0.0%)	1 (0.9%)	8 (15.1%)	7 (13.5%)	15 (14.3%)
Maximum Achieved Change (Dieting)						
N/A	6 (11.5%)	7 (12.3%)	13 (11.9%)	5 (9.4%)	4 (7.7%)	9 (8.6%)
No change	20 (38.5%)	29 (50.9%)	49 (45.0%)	12 (22.6%)	24 (46.2%)	36 (34.3%)
Initiated	26 (50.0%)	20 (35.1%)	46 (42.2%)	23 (43.4%)	7 (13.5%)	30 (28.6%)
Maintained	0 (0.0%)	1 (1.8%)	1 (0.9%)	13 (24.5%)	17 (32.7%)	30 (28.6%)
Maximum Achieved Change (Physical Activity)						
N/A	1 (1.9%)	4 (7.0%)	5 (4.6%)	2 (3.8%)	4 (7.7%)	6 (5.7%)
No change	37 (71.2%)	34 (59.6%)	71 (65.1%)	21 (39.6%)	24 (46.2%)	45 (42.9%)

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	3 Months			6 Months		
	New Assessment	**Usual Practice**	**Overall**	**New Assessment**	**Usual Practice**	**Overall**
Initiated	14 (26.9%)	18 (31.6%)	32 (29.4%)	21 (39.6%)	13 (25.0%)	34 (32.4%)
Maintained	0 (0.0%)	1 (1.8%)	1 (0.9%)	9 (17.0%)	11 (21.2%)	20 (19.0%)

Percentages were calculated using the number of patients available from the relevant population as the denominator, i.e. excluding patients with missing data for that variable.

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Table 4

Primary outcome of uptake of lifestyle referral

	Unadjusted* Odds Ratio	(95% Confidence Interval)	Adjusted† Odds Ratio	(95% Confidence Interval)
3-Months				
Uptake	6.52	(1.66 to 37.82)	6.85	(1.65 to 41.70)
Initiation	1.38	(0.55 to 3.52)	1.28	(0.51 to 3.27)
Maximum Achieved Change (Overall, Ordinal)	0.68	(0.30 to 1.53)	0.74	(0.32 to 1.69)
6-Months				
Uptake	7.20	(1.48 to 69.84)	7.12	(1.36 to 72.73)
Initiation	1.86	(0.64 to 5.77)	1.76	(0.60 to 5.47)
Maximum Achieved Change (Overall, Ordinal)	0.46	(0.22 to 0.98)	0.47	(0.22 to 1.01)

*Exact logistic regression is used except for participation, where a large-sample proportional odds model was fitted.

†Analyses are adjusted for baseline risk factor=smoking, drinking or weight.