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Interdisciplinary lifestyle intervention for weight management in a community population (HealthTrack study): study design and baseline sample characteristics

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Background Integrating professional expertise in diet, exercise and behavioural support may provide more effective preventive health services but this needs testing. We describe the design and baseline results of a trial in the Illawarra region of New South Wales, Australia. **Methods** The HealthTrack study is a 12 month randomised controlled trial testing effects of a novel interdisciplinary lifestyle intervention versus usual care. The study recruited overweight and obese adults 25-54 years resident in the Illawarra. Primary outcomes were weight, and secondary outcomes were disease risk factors (lipids, glucose, blood pressure), and behaviour (diet, activity, and psychological factors). Protocols, recruitment and baseline characteristics are reported. **Results** Between May 2014 and April 2015, 377 participants were recruited and randomised. The median age (IQR) of the mostly female sample (74%) was 45 (37-51) years. The sample comprised obese (BMI 32 (29-35) kg/m²) well educated (79% post school qualifications) non-smokers (96%). A high proportion reported suffering from anxiety (26.8%) and depression (33.7%). Metabolic syndrome was identified in 34.9% of the sample. **Conclusions** The HealthTrack study sample was recruited to test the effectiveness of an interdisciplinary approach to preventive healthcare in self-identified overweight adults in the Illawarra region. The profile of participants gives some indication of those likely to use services similar to the trial design.

Disciplines

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Interdisciplinary lifestyle intervention for weight management in a community population (HealthTrack study): Study design and baseline sample characteristics

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The authors declare they have no conflict of interest

Abbreviations: 4DFR: Four Day Food Record; ACT: Acceptance and Commitment Therapy; AEP: Accredited Exercise Physiologist; APD: Accredited Practising Dietitian; CCM: Chronic Care Model; GP: General Practitioner; IHMRI: Illawarra Health and Medical Research Institute; IPAQ: International Physical Activity Questionnaire; SOPs: Standard Operating Procedures

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Results: Between May 2014 and April 2015, 377 participants were recruited and randomised. The median age (IQR) of the mostly female sample (74%) was 45 (37-51) years. The sample comprised obese (BMI 32 (29-35) kg/m²) well educated (79% post school qualifications) non-smokers (96%). A high proportion reported suffering from anxiety (26.8%) and depression (33.7%). Metabolic syndrome was identified in 34.9% of the sample.

Conclusions: The HealthTrack study sample was recruited to test the effectiveness of an interdisciplinary approach to preventive healthcare in self-identified overweight adults in the Illawarra region. The profile of participants gives some indication of those likely to use services similar to the trial design.

Keywords: interdisciplinary; study protocol; clinical trial; health services; overweight

Introduction

Chronic lifestyle related diseases such as cardiovascular disease, type 2 diabetes, kidney disease, and some cancers are prevalent in the community as are mental health and eating disorders. Excessive weight contributes to the risk of all these conditions [1-4], and obesity contributes to co-morbidities such as hypertension, osteoarthritis, asthma, sleep apnoea, chronic back pain, sexual dysfunction and depression [1, 5].

The prevalence of overweight and obesity among Australians has been increasing over the last three decades with 60% of adults considered overweight or obese [1, 6]. Of these adults, more males (42%) than females (35%) tend to be overweight and 28% of both males and females are obese [6]. In healthy Western populations body weight gradually increases with increasing age, although the trend slows after age 50-60 years [7, 8]. Men < 40 years and women < 50 years tend to experience the most weight-gain, and after 70years, some weight loss is common [9]. For most overweight and obese adults, long-term supportive management requires regular monitoring and lifestyle change through a tailored approach [1]. Weight loss of at least 5% of initial body weight is sufficient to reduce health risks, by lowering blood pressure and reducing the risk or delaying progression of type 2 diabetes [1]. Interdisciplinary services are effective in managing weight loss overall, and repeated or more intense lifestyle interventions may be necessary for long-term weight management [1]. Research in this area invariably includes diet and exercise, and to some extent psychology. It also emphasises the importance of personal contact with health professionals [10]. From the healthcare delivery perspective, there have been calls for high value interdisciplinary clinical services which focus on team-based care for chronic disease prevention [11]. While weight loss is likely to be maintained with continued intervention [12] (i.e. what to do), there is a great need for research on the intervention design or protocol (i.e. how to do it) [13].

Exploring how health professionals might adapt into effective teams underpins several models of chronic disease management, in particular the Chronic Care Model (CCM) [14]. While there are a number of approaches to weight management available (including those delivered by the private sector, and broad public health media campaigns) the CCM refers directly to clinical health services, the focus of this research. The CCM involves integration of components of the health care system, including that provided by medical, nursing and allied health professionals. Self-management is also a central component of the CCM, with ongoing support via face-to-face or telephone contact included to facilitate behaviour change.

The HealthTrack Lifestyle intervention trial brings together the disciplines of nutrition and dietetics, exercise physiology, psychology, medicine and nursing to test the effect of an integrated approach to lifestyle intervention. Supported by the Illawarra Health and Medical Research Institute (IHMRI, collaboration between the University of Wollongong and the Illawarra Shoalhaven Local Health District) it is charged with addressing chronic disease risk in the region. The innovation is that the client interface involves a single health practitioner but all 3 lifestyle practitioners (dietitian, exercise physiologist, psychologist) have input into the design. The regional setting enables the study to serve as a case study for translational purposes. The primary outcome is weight, but there are multiple secondary outcomes relating to chronic disease risk. The main hypothesis is that a novel interdisciplinary approach to individualised lifestyle intervention will result in greater weight loss compared to usual care. In this study, usual care was based on a primary care model where guidance on diet and physical activity, is delivered by a clinical nurse practitioner using general tools such as dietary and physical activity guidelines for the population. For study design purposes the amount of time spent with participants and the frequency of interaction (intensity of intervention) was the same for all groups. Finally, self-managing change includes making healthier food choices, and study designs include various approaches to supporting dietary change. In the PREDIMED trial, for example [15], food supplements of mixed nuts or olive oil were provided to assist with compliance with the Mediterranean diet, and this in itself was argued to influence the outcomes of the trial [16]. Based on previous experience with supplementing weight loss trials with walnuts [17, 18], we added a third arm to examine whether supplying a healthy food (walnuts) enhanced outcomes. This protocol paper describes the study design, implementation methods and baseline recruitment for the HealthTrack trial.

Materials and methods

Study plan

Trial design The HealthTrack study was originally designed as a 2 arm parallel randomised controlled trial of health practitioner delivered advice conducted over 12 months. With additional industry funding, a second intervention arm was added to test the effect of whether providing a sample of a healthy food (walnuts) would enhance the effect of the intervention. The two experimental interventions were designed to include individualised dietary advice and categorised physical activity advice based on discipline based assessments. As there is

evidence that diet is important for initial weight loss and exercise is important for weight maintenance [19], this advice was delivered by the dietitian as the single practitioner. Individualised exercise questions were answered via discussions with an exercise physiologist, but delivered to the participant by the dietitian. Follow up scripted phone calls were provided by health coaches trained by psychologists. The control intervention comprised delivery of general advice and follow up support by a nurse practitioner. The intensity of intervention was the same for all arms of the study, with all groups prescribed the same number of visits and phone contacts. The design, conduct, and reporting of this study adhered to the Consolidated Standards of Reporting Trials (CONSORT) guidelines [20]. Ethics approval was provided by the University of Wollongong/Illawarra Shoalhaven Local Health District Human Research Ethics Committee (Health and Medical) (HE 13/189) and the study is registered with the Australian and New Zealand Clinical Trial Registry (ANZCTR N12614000581662). A flow diagram of recruitment, screening and clinic visits is provided in **Fig 1** and described in detail in the following sections.

Primary and secondary outcomes: The primary outcome was body weight (kg). Secondary outcomes were fasting blood lipids, glucose and HBA1c and systolic blood pressure. Secondary outcomes relating to behaviour include dietary intake, measures of physical activity and psychological wellbeing. Urinary sodium levels were assessed as a marker of sodium intake.

Study management: The study was designed and implemented by a large multidisciplinary clinical research team. The developmental stage of the study resulted in an implementation plan negotiated across five healthcare disciplines (medicine, nursing, dietetics, exercise science and psychology) in consultation with community members, statisticians, and external review panels. The senior scientific investigator and clinical investigator oversaw all aspects of the study. The study co-ordinator (post-doctoral research fellow) managed the development of protocols, data management systems and quality audit procedures, developed and implemented in collaboration with researchers, including those from information technology. The full research team meets monthly and senior investigators reported on a regular basis to the funding bodies.

The study administrator managed recruitment and organised face to face counselling at the clinic and follow up telephone calls for the control group . The clinical trials

manager/dietitian managed the scheduling of the 4 other Accredited Practising Dietitians (APDs) for assessments and counselling. For each participant, a different APD that was blinded to study allocation undertook assessments to the one providing counselling, to reduce the risk of cross-contamination between study arms.

Participants, inclusion and exclusion criteria: The study population was drawn from the Illawarra community, a major coastal region 70km south of Sydney, Australia. The region has a population of approximately 294,083, with a median age of 38.9 years [21]. The prevalence of obesity in the Illawarra is estimated to be higher than the Australian average [22]. Inclusion criteria were: permanent residents of the Illawarra region, adults aged 25-54 years, and with a BMI in the range 25-40kg/m². Exclusion criteria were: unable to communicate in English; have severe medical conditions, an impaired ability to participate in study; or have other medical conditions thought to limit survival to 1 year; suffer from immunodeficiency; have reported illegal drug use or regular alcohol intake associated with alcoholism (>50g/day); or have difficulties or major impediments to participating in the components of the study.

Recruitment: Recruitment is complete having utilised an extensive network of community organisations and workplaces. These included the general media (online communications and local newspapers), the university and health services channels, primary healthcare networks, local councils and major workplace environments including hotels, community services and heavy industry. News of the study is a permanent feature in the local media, including a regular column written by various health disciplines and a regular blog of experience by a high profile participant. Ongoing information reflects discussion on general health issues rather than study specific matters to avoid cross-contamination between study arms.

Screening and enrolment: Screening, enrolment and randomisation are complete. Participant identification and enrolment was managed by blinded study investigators not involved in the provision of the intervention. Interested participants contacted the study administrator via email or telephone, and were sent an individual access code for the online health survey. The study administrator prepared summaries of the self-reported health survey data for review by the senior investigators for assessment of eligibility. The senior clinical investigator identified any relevant medical problems and advised on requirements for GP clearances required for participation. Eligible participants were then contacted by the clinical trial manager to attend

the IHMRI Clinical Trials Research Unit for a baseline assessment conducted by an APD and a referral to the laboratory service for pathology tests was provided. Results of the baseline assessment and pathology tests were reviewed at the next screening meeting to ensure eligibility for randomisation. Any further medical issues were identified by the clinical investigator and written communications and copies of pathology results were prepared for participants' GPs.

Randomisation was conducted after the second screen for eligibility and performed remotely by an investigator unrelated to the clinic using a computer generated randomisation sequence (STATA V12, StataCorp LP, College Station Tx). The randomisation was stratified according to sex and BMI (low BMI: ≤ 30 and high BMI : >30). Randomisation was performed in randomly allocated blocks of 3, 6 or 9. The randomisation list was provided to the study team who added eligible participants sequentially for each of the strata. The randomisation and participant database was only accessible by the HealthTrack study coordinator and administrator for security. Participants were blinded to their randomised allocation and only advised they would be seen by a health practitioner.

Screening assessments: The screening survey included demographic data as well as questions reflecting similar data obtained from current health surveys applied to this population and included tailored questions targeting additional areas of concern, such as health service utilisation. It included self-reported height and weight, and questions relating to food habits in the form of short questions to measure specific aspects of food habits that are relevant to overweight and obesity, including the amount of fruit and vegetables consumed, type of milk consumed, and frequency of red meat consumption [23]. It also included psychological questions including Emotional eating (3 questions), Brief stigmatising (10 questions), and stages of change – exercise (4 questions). The screening survey will be completed again at the end of the trial. At the clinic, body weight was measured as indicated below. Height was measured using a stadiometer to measure height rounded to the nearest millimetre. Waist circumference was measured using standard procedures described by the International Standard of Advancement of Kinanthropometry [24]. Body fat was taken from the instrumentation applied for body weight assessment. Each week the exercise physiologist would review referrals and provide the necessary information either within the clinic database or via information/pamphlets placed into the participant files for the dietitian. A sub maximal exercise test was applied using the Queen's College Step Test which uses recovery heart rate to calculate participant's physical fitness levels. It has proven validity and reliability in this

context [25]. After resting for 5 minutes a pre-exercise heart rate was recorded via a chest monitor. Exercise commenced for 3 minutes whereby participants continually stepped up and down onto a 41.3cm box, at a set step rate (men 24 steps/ minute and women 22 steps/minute). On completion, recovery heart rate was then recorded at 0, 15, 30, 60 and 150 seconds post-exercise and the mean VO₂ max value was used (using the formula Men $111.33 - 0.42 \times [\text{recovery heart beats/minute}]$; Women: $65.81 - 0.1847 \times [\text{recovery heart beats/minute}]$).

Clinic visits: The number of visits and phone contacts were the same for all participants in the study regardless of group allocation. To minimise risk of cross-contamination, control participant visits were conducted in different clinic rooms to those used for intervention participants. After baseline assessment, participants attended the clinic on a monthly basis for 3 months and then on a quarterly basis until the end of a 12 month period. In between visits phone contact was made as an additional motivation (**Table 1**). Participants were not provided monetary incentives for their participation. In the case that participants withdrew from the study, data on the reason for withdrawal were collected.

Measurement of outcomes

Body weight (kg) was measured in an upright position in minimal clothing and without shoes using scales with a bio-electrical impedance component to also estimate body fat (%) (Tanita TBF-662, Wedderburn Pty Ltd, Ingleburn, NSW, Australia).

Pathology tests: Fasting blood lipids (cholesterol, LDL, HDL, Trig), fasting blood glucose, and serum HBA1c was collected and tested through a registered Pathology service (Southern IML Pathology). Participants were asked to collect a 24 hour urine sample and deliver it to Southern Pathology. A container and instruction sheet was provided at the same time as the pathology forms. The urine sample was used to test sodium, potassium and creatinine excretion as the gold standard for sodium intake.

Systolic blood pressure (SBP) and diastolic blood pressure (DBP) was measured using the Omron BP-203RPEIII VP-1000 device (Omron Health Care, Kyoto, Japan). Measurements were collected at the end of 5 min resting period in a supine position. Arterial stiffness (baPWV) and arterial occlusion (ankle brachial index) data were also collected from device.

Self-reported dietary intake was assessed using diet history interview (DH) conducted by an APD at clinic visits and 4 day food records (4DFR) including one weekend day were

completed by participants after the clinic visit. Participants were advised on recording all foods consumed including amounts and recipes using booklets provided. For the DH, participants were requested to describe the usual types and amounts of food and drink consumed using a validated protocol [26]. The details were recorded on a standardised diet history form with cues for the dietitian for checking completeness. Dietary data were calculated using FoodWorks nutrient analysis software (Version 7; Xyris Pty Ltd, Kenmore Hills, QLD, Australia, 2012), based on the AUSNUT 2007 food composition survey database [27]. Different nutrition trained individuals were responsible for entering and checking dietary data.

Physical activity was assessed using the International Physical Activity Questionnaire (IPAQ) short form survey questions [28], and questions on participants' perceptions on how much physical activity is necessary for a healthy lifestyle. A scientific grade pedometer was used (Yamax Digiwalker SW200, Pedometers Australia). Participants were requested to wear the pedometer and record steps daily at the same time as completing the 4DFR. Below 500 steps/day or above 30,000 steps/day were considered to be implausible in line with published cut-offs [29]. A sub-sample of participants were assigned an accelerometer and trained in its use (placement on wrist, record keeping). They were asked to wear the accelerometer on two week days and one weekend (to coincide with the 4DFR).

Psychological profile: A composite psychological assessment was conducted using items from validated questionnaires to test for psychological flexibility, diet flexibility, and exercise motivation. This assessment included items relating to Physical and Mental Health SF-12 (12 questions) [30], Acceptance and action (11 questions) (AAQII) [31], Positive Emotional Well-being (3 questions) [32], Depression anxiety stress short form (DASS – 21; 21 questions) [33], Emotional eating (3 questions) [34], Rigid control of diet (R16; 16 questions) [35], and Motivation for exercise (24 questions) [36, 37].

Intervention group procedures

Intervention health practitioner: An APD provided face to face advice based on an individualised program of diet, physical activity and behavioural support for weight loss and maintenance. These clinic visits were followed up with phone calls from a health coach. Usual diet and physical activity patterns were assessed by the dietitians and discussed with exercise psychologists (if needed) in the team who developed plans to assist participants to adapt to healthier eating/exercise options targeting weight management.

Intervention dietary advice: Participants were given individualised dietary counselling addressing their unique patterns of food choice. Dietary modelling, a process of constructing dietary plans with prescribed energy and nutrient values and based on food combinations, was undertaken to ensure the advice given to participants matched the targeted requirements for their status. Advice was based on the prescription of the number of food choices from food categories defined in the Australian Guide to Healthy Eating [38], individualised with reference to usual food habits and energy requirements. Dietary support material on seasonal foods, recipes and shopping lists was developed along the lines of the PREDIMED trial [39]. One arm of the experimental group was provided with 30g of walnuts per day for the length of the study. The energy value of the walnuts provided was modelled into the overall diet plan so as not to provide extra energy.

Intervention physical activity: the intervention targeted increased physical activity levels and reduced accumulative minutes of daily sedentary behaviour. Opportunities that arose in leisure, occupation and household activities were identified. A 2 page hand-out was provided to participants to communicate current public health guidelines and establish goals for healthy lifestyles.

Intervention psychological support: psychological support was provided by health coaches from health practitioner backgrounds and trained by the senior psychologists. Telephone appointments with health coaches were organised by health practitioners at the one month counselling visit and thereafter. A health coaching workbook was provided to participants at this visit, to complement the verbal support provided by health coaches. In line with Acceptance and Commitment Therapy [40] the themes of mindfulness, motivation and self-compassion were used to support the achievement of the dietary and exercise goals. Trained health coaches provided scripted behavioural support of 15 min duration via regular phone coaching (4 times over 12 mo – between 1-3mo, 3-6mo, 6-9mo, 9-12mo), audio recorded for fidelity. Health coaches only contacted the participant at the time of the scheduled health coach telephone call, introduced themselves and commenced the session using scripted texts. The sessions were audio recorded and the study psychologists oversaw the counselling to assure fidelity with Acceptance and Commitment Therapy (ACT) and the content of the health coaching workbooks.

Control group procedures

Control health practitioner: Participants received general health policy advice and social support from a clinical nurse practitioner.

Control dietary advice: Similar to the Women's Health Initiative's Dietary Modification trial [41], participants were given copies of Dietary Guidelines [38] plus other health related material. Participants were asked to reflect on their current diets and identify changes in their food choices that might align their usual eating patterns more in accordance with dietary guidelines.

Control physical activity: The participants received basic physical activity advice in line with the current Australian Physical Activity Guidelines [42]. They were encouraged to be physically active almost every day with low to moderate intensity communicated as activities that make you 'at-least huff or puff'.

Psychological support: Phone calls are made at the same intervals by the study administrator to remind the participant of the next appointment and ask if they have any concerns or problems. If so these are noted and referred to the nurse counsellor who followed up at the next clinic visit.

Statistics

Power calculations: Several power calculations were conducted using SAS PROC POWER using a range of standard deviations from 3.5 to 5. One hundred and twenty subjects per group were considered sufficient to detect a minimum between group weight loss difference of 2.7kg as significant with 80% power and a two tailed α of 0.025 and 0.017 (adjusted for planned contrast between control and each treatment group and a between treatments comparison). This assumes ~25% post randomization dropout rate (using available literature and our own experience).

Primary analyses: The analysis at the end of the 12 month follow-up will be conducted using a linear mixed model. The use of the mixed model allows partial datasets incorporating all available data regardless of whether or not the subject completed the study. The planned contrasts are between the control and the intervention groups. Sensitivity analyses will be considered if missing data is substantial.

Results

Protocols: Eleven Standard Operating Procedures (SOPs) were developed for all the operational elements described for this study and are being implemented. The study was launched in May 2014 by the Lord Mayor of Wollongong city. Recruitment for the HealthTrack study began on 9th May 2014 and concluded on 28th April 2015. Screening surveys were sent to 718 people of whom 620 provided consent and 377 were randomised (**Fig 2**).

Recruitment: After consent and before randomisation 243 volunteers left the study (167 being ineligible, 76 withdrawals). This occurred in two phases characterised by survey completion and baseline assessment. Amongst those who were not eligible to proceed to baseline assessment (n=161) the number of morbidly obese volunteers (BMI>40kg/m²) was much greater than for volunteers with low BMIs (<25kg/m²) (51.6% vs7.5%). In addition n=24 participants (14.9%) were excluded because of a male and female partner wishing to participate. After completing the survey “time constraints” were listed as the primary reasons for withdrawing by 16/19 volunteers.

After the baseline assessment a further 57 volunteers withdrew, with 24 of these not completing the pathology testing. The proportion of males and females withdrawing was similar to the proportion participating (3:16 pre-assessment and 15:42 post assessment). Only a further 6 were deemed ineligible, with implausible reported BMIs (much higher than measured at baseline), problems with consuming nuts or medical reasons. Of the 377 randomised participants in the trial, 125 were allocated to the intervention arm, 126 to the intervention arm + walnuts and 126 to usual care (**Fig 2**). As of the 23rd July 2015, n=17 participants had completed the 12 month assessment, n=97 were at 9 months, n=144 at 6 months, and n=213 were at 3 months.

The greatest number of surveys was sent out following the Lord Mayor’s launch of the study in May 2014. There were two more peaks of higher response, in September 2014 and February 2015. These coincided with concerted recruitment drives involving calls to the network of contacts in the region, particularly major worksites. Recruitment fell short of the predicted completion date of November 2014 which necessitated the second call to workplace networks in the New Year. This combined with an item in the local television evening news enabled recruitment to be completed in March 2015. Randomisation followed recruitment closely (**Fig 3**). On average, over the time-course of recruitment 65 surveys were sent out each month, 39 were deemed eligible and 34 participants were randomised into the study.

At the screening meeting, the exclusions for inability to participate in the study was further identified. Additional communications with GPs was required for confirmation of participant-reported sleep apnoea and subsequent treatment. Participants were excluded if diagnosed and untreated as this was determined to be a major impediment to participation in the study. For the same reason, participants with type 1 diabetes were also excluded due to the added constraints on dietary modifications. Where both a male and female partner volunteered, only one was accepted into the study so that randomisation did not present an impediment to participation (due to a potential to compromise blinding).

Baseline data: The sample was obese (median BMI 32kg/m², interquartile range [IQR] 29, 35), with a high percent body fat (median 41% IQR 36, 46) and large waist circumference (103cm IQR 96, 112). Demographic data show a largely female sample (74%) that is well educated (trade/apprenticeship 5.3%, certificate/diploma 28.9%, university degree 30.2%, post graduate degree 20.2%). The median age was 45yr (IQR 37, 51). Participants were predominantly Australian born (82%), and 2% were of Aboriginal or Torres Strait Islander origin. Only 4% were current smokers.

With reference to standards, clinical data show the median value for the sample was within normal ranges for blood glucose levels, blood lipid levels and blood pressure measurements. However, 13.3% reported taking antihypertensive medication, 8.5% hypolipidemic medication, 17% antidepressant or antianxiety medication, and 4% hypoglycemic medication or insulin (**Table 2**). Combining risk factors showed that 34.9% of the sample were classified with Metabolic Syndrome according to the 2009 Joint Scientific Statement [43] and using the Adult Treatment Panel III waist circumference standard [44]. One third of the sample report they suffered from depression and slightly less (26.8%) from anxiety (**Table 2**).

Compared to the standard reference ranges the study sample reported having a normal quality of life (physical and mental) and physical activity level, but high levels of anxiety (score 11, IQR 7.19; reference standard 3.53). They report being active and consume an average amount of protein in the diet. Their diet profile tends to tend toward high fat (34.5% energy, IQR 30.9, 38.4) and low carbohydrate (41.9% energy, IQR 37.8, 46.1) (**Table 3**).

Discussion

The HealthTrack study represents significant developments in research for both interdisciplinary approaches to lifestyle intervention and the development of preventive

health services for a regional population. This is a well organised study lead by a scientific and clinical senior investigator team working with a clinical unit of supervisors and sessional staff who deliver the clinical interface. The involvement of researchers who also enable the contribution and supervision of research students represents an added value for the research investment. Effective role delineation was clearly important for implementing the trial while maintaining confidentiality and blinding, as well as managing the flow of participants through the schedules (Fig 1). Standard Operating Procedures were critical in enabling clarity and assuring quality aligned with good clinical practice principles.

If this study were to reflect actual clinics, the recruitment profile suggests that people may be more likely to access healthy lifestyle services when the weight problem is greater. Despite addressing all overweight community members, and communicating a broad message on healthy lifestyles, the recruitment sample was characterised as obese (median BMI 32kg/m²). In addition, after the screening survey, morbidly obese (BMI >40kg/m²) accounted for 51.5% of the volunteers excluded from the study. Morbidly obese individuals were not included in this study due to the likelihood of other co-morbidities being present in this group, however, this result indicates a need for lifestyle support for these people in the community which is not reflected in the current study. The remainder of the exclusions were varied, but highlight the important role of the senior clinical investigator in undertaking medical reviews and providing medical oversight.

Despite the broad reach of promotions for recruitment (including in predominantly male worksites) the study sample was only 30% male. This does not reflect the overall Australian profile where equal numbers of males and females appear in the obese category (28%) [1]. It may be that a clinical service delivery model of this type better suits females or that they are more willing to act on disease risk reduction than men. Research suggests males are less likely to access primary healthcare services than females, particularly preventive healthcare [45]. In addition, research suggests that females were more likely to have seen a general practitioner in the previous 12 months than males (87% versus 75% respectively) [46].

Health service delivery models and personal commitment could also be seen as major factors in the recruitment phase. The predominant citation of time constraints (16/19 after completing the survey and 54/57 after pathology testing) implies incongruence with what the service has to offer. There may also be conflict with the personal needs and goals, and external influences may act as detractors. In some of our research from previous trials,

participants have described how external influences over which they have little control compete with their desires to adapt to the healthy behaviours they have signed up for. They are able to articulate desired health outcomes, although these do not always align exactly with those of the trial. Importantly an inability to achieve their desired outcomes affects their sense of wellbeing [47]. More research is needed in this area, particularly as we have noted that the HealthTrack sample has a high rate of anxiety and depression.

Despite the experiences described above, the recruitment process for the HealthTrack study successfully achieved targeted numbers within a 12 month period, producing a baseline profile suitable for testing effects of a novel interdisciplinary lifestyle intervention. The links with key community organisations and the local media proved critical in attracting participation. A well supported launch of the study generated substantial interest, but ongoing contact at varying intervals was also required to complete recruitment.

A limitation of the study is the greater number of females recruited. We have noted bias in sex distribution in previous trials [48, 49] and are aware that we will have to consider this in terms of generalisability of results. The study sample indicates that educated obese women in particular are willing and able to undertake the program of services. While weight is the primary outcome, the underlying principles behind the study relate to health and wellbeing. The median age of the sample address the prevention of chronic disease, bearing in mind that the consequences of risk factors (including overweight) are likely to take their toll in the ensuing years. The 34.9% prevalence of Metabolic Syndrome [43] in the study is higher than the 26.1% observed for the Australian population using a similar definition [50]. This would be expected from a targeted sample, but it underpins the clinical relevance for a third of participants in cardiovascular disease prevention. Likewise, the study will provide insights into the effects of lifestyle intervention in the amelioration of hypertension. This is particularly the case as 24hr urinary sodium measurements will give some indication of an individual's sodium intake, a target for dietary change to address high blood pressure levels in the community [38].

The high rate of depression and anxiety reported in the sample is of concern and underlines the value of the integrated approach to lifestyle change brought by the expertise of the interdisciplinary team. It is likely that the individualised approach to diet will improve the reported diet quality of participants as has been our experience in the past [51]. While the

participants report being active, greater levels of activity are likely to be required for sustained weight loss [19]. Further research is needed for a follow up study in which the roles of the APD and AEP are reversed with a greater focus on individualised exercise prescription and support for already negotiated dietary changes.

In summary, the HealthTrack study addresses the values of institutional links within a regional community, and of health disciplines associated with lifestyle related disease working together to support the health of community members. There have been a number of learnings from initiating the study, with implications for how this research may translate into practice within health services.

The study shows it is possible to develop protocols that reflect the practices of medical and allied health practitioners in the primary care setting. Effective collaboration between lifestyle experts - exercise, dietetic and psychology disciplines in particular means that health practitioners can work together for the individual helping to overcome the problem of seeking multiple services with varying accessibility. The protocols developed for the study provide direct pathways to practice and analyses will contribute much needed evidence for clinical practice guidelines. The research targets a clinical population where the individual effects on over 300 people are highly relevant. The participant profile itself provides insights into who might use these types of services and where there may be additional needs. Although the recruitment period was completed within a 12 month period, the variation in rate of and the extra effort required to finalise numbers has implications for further clinical research in the area, as well as the marketing of services should they be developed.

Finally, as a whole this study will generate new and important data exposing the impact of a novel health service in a defined regional population, and as such forms a significant case study for planning localized preventive health clinics. The combination of data that will be generated is significant for holistic preventive health services. The set of measurements in anthropometry, physical activity, dietary intake, pathology/biomarker assessments and relevant aspects of mental health and quality of life enable the healthcare team to monitor specific aspects of physical and mental health and wellbeing, and to consider the inter-relationships between them. Not only does the research reflect an effective partnership between the university, health services and local community, it also works with the considerable talent of research students to maximize the learnings for the community and for health services practice generally. Like all good research it is likely to generate more

hypotheses and study concepts that address the scope of the problem of chronic disease in the community, but this is a helpful start.

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Tables and Figures:

Table 1.

Summary of procedures completed at each time point in the HealthTrack study.

Assessments	Visits												
	Screening survey	Baseline Ax	Baseline Co	W4 Co	W8 Co	W12 Ax	W12 Co	W24 Ax	W24 Co	W36 Ax	W36 Co	W48 Ax	W48 Co
Consent		X											
Survey	X											X	
Physiological assessment		X				X						X	
Anthropometric assessment		X		X [□]	X [□]	X		X		X		X	
Diet history and 4 day food record		X				X		X		X		X	
Psychological and Behaviour Assessment		X				X						X	
Physical activity assessment		X				X		X		X		X	
Blood pathology		X				X ^{□□}		X ^{□□}		X ^{□□}		X ^{□□}	
24 h urine pathology		X				X						X	
MSU		X											
Dietary/exercise counselling			X	X	X		X		X		X		X
Health coaching (intervention arm only)				X			X		X		X		
Medical review		X				X		X		X		X	

Abbreviations: W: week; Ax: assessment; Co: counselling.

Physiological assessment includes: Blood pressure and Queen's College Step Test, ankle brachial index.

Anthropometric assessment includes: height (baseline only), weight, BMI, % body fat, waist & hip circumference. * means only weight and body fat %.

Psychological & behaviour assessment: SF12 — Quality of Life, Behavioural Regulation in Exercise Questionnaire (BREQ), Rigid Control Scale (RC16), Acceptance and Action Questionnaire for Weight-Related Difficulties (AAQ-W), Depression Anxiety Stress Scale-21 (DASS-21).

Physical activity assessment: IPAQ survey, pedometer, accelerometer (subset at 0, 12 only), heart rate monitor (0, 3, 12 only).

Baseline blood pathology includes: EUC (electrolytes, urea, creatinine), FBC, fasting glucose, HbA1c, fasting lipids (cholesterol, triglycerides, LDL and HDL cholesterol), urate.

** 3, 6, 9 & 12 month blood pathology includes: fasting glucose, HbA1c, fasting lipids (cholesterol, triglycerides, LDL and HDL cholesterol).

24 h urine includes: urate, sodium, potassium, creatinine.

MSU includes: albumin:creatinine and M/C/S (including haematuria).

Table 2.

Clinical profile of the HealthTrack study sample.

Clinical variable	Baseline result	Standard reference ranges
Medical *n = 375		
Systolic blood pressure (mmHg)	124 (114, 133)	< 140
Diastolic blood pressure (mmHg)	73 (65, 79)	< 90
Number reporting comorbidity (%)		
Skin cancer (not melanoma) *n = 360	11.7	
High blood pressure *n = 358	25.2	
Diabetes *n = 355	5.6	
Asthma *n = 355	21.0	
Hayfever *n = 357	28.1	
Depression *n = 359	33.7	
Anxiety *n = 353	26.8	
Sleep apnoea *n = 345	5.6	
Number reporting medication (%) *n = 377		
Antihypertensive	13.3	
Hypoglycemic/insulin	4.0	
Hypolipidemic	8.5	
Antidepressant/antianxiety	17.0	
Pathology		
Glucose (mmol/L) *n = 375	5.2 (4.9, 5.7)	3.6–6.0
HbA1c (%) *n = 377	5.2 (4.9, 5.4)	4.0–6.0
Total cholesterol (mmol/L) *n = 376	5.1 (4.6, 5.8)	2.3–5.5
Triglycerides (mmol/L) *n = 376	1.2 (0.8, 1.6)	0.0–2.0
HDL (mmol/L) *n = 376	1.4 (1.2, 1.7)	1.0–3.0
Cholesterol/HDL ratio *n = 375	3.7 (3.0, 4.4)	0.0–4.5
LDL (mmol/L) *n = 372	3.1 (2.6, 3.7)	0.5–3.5

Table 3.

Mental health and wellbeing, physical activity and dietary intakes at baseline.

Lifestyle characteristics	Baseline result (n = 377) *unless otherwise stated	Standard reference ranges
Psychological assessment		
Quality of Life (SF12) physical summary *n = 375	50 (45, 55)	44.3–56.7
Quality of Life (SF12) mental summary *n = 375	48 (40, 54)	43.5–57.1
Depression Anxiety Stress Scale (DASS-21)_total	11 (7, 19)	3.53 [25]
Acceptance and Action Questionnaire for Weight-Related Difficulties (AAQW) *n = 313	83 (70, 100)	
Physical activity		
IPAQ		
Total MET (min/week) *n = 371	960 (462, 1822)	500–1000
Weekly kJ MET min × weight *n = 371	6000 (2791, 11,276)	
Steps per day *n = 295	7222 (5395, 9523)	> 7000
Dietary intake *n = 340		
Energy (kJ)	8711 (7294, 10,352)	
Protein (%)	19.2 (17.2, 22.2)	15–25% [44]
Fat (%)	34.5 (30.9, 38.4)	20–35% [44]
Carbohydrate (%)	41.9 (37.8, 46.1)	45–65% [44]
Alcohol (%)	0.13 (0.0, 3.3)	
Fibre (g)	23.4 (18.4, 29.1)	

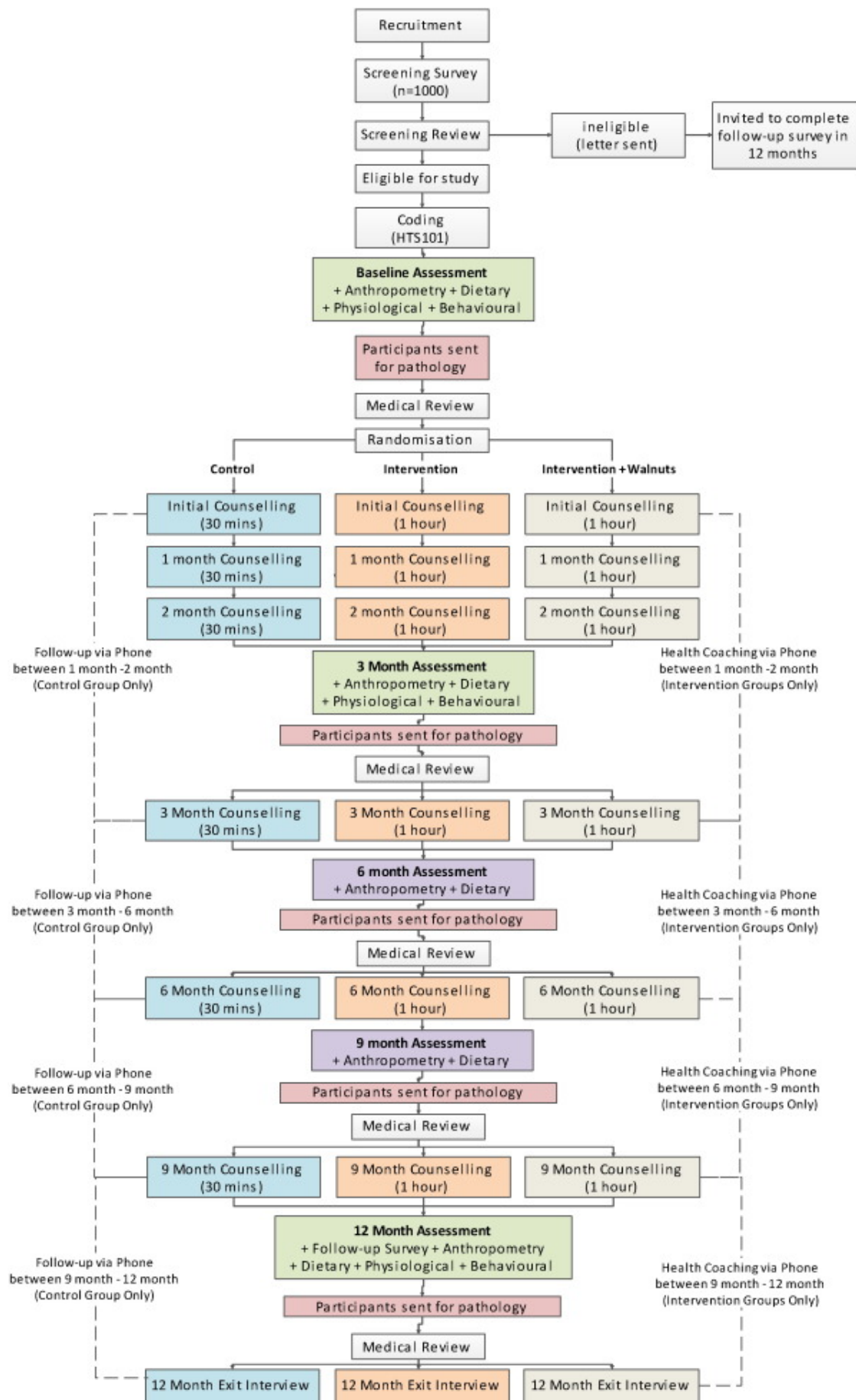


Fig. 1.

Flow diagram for recruitment, survey, randomisation, and study finalisation.

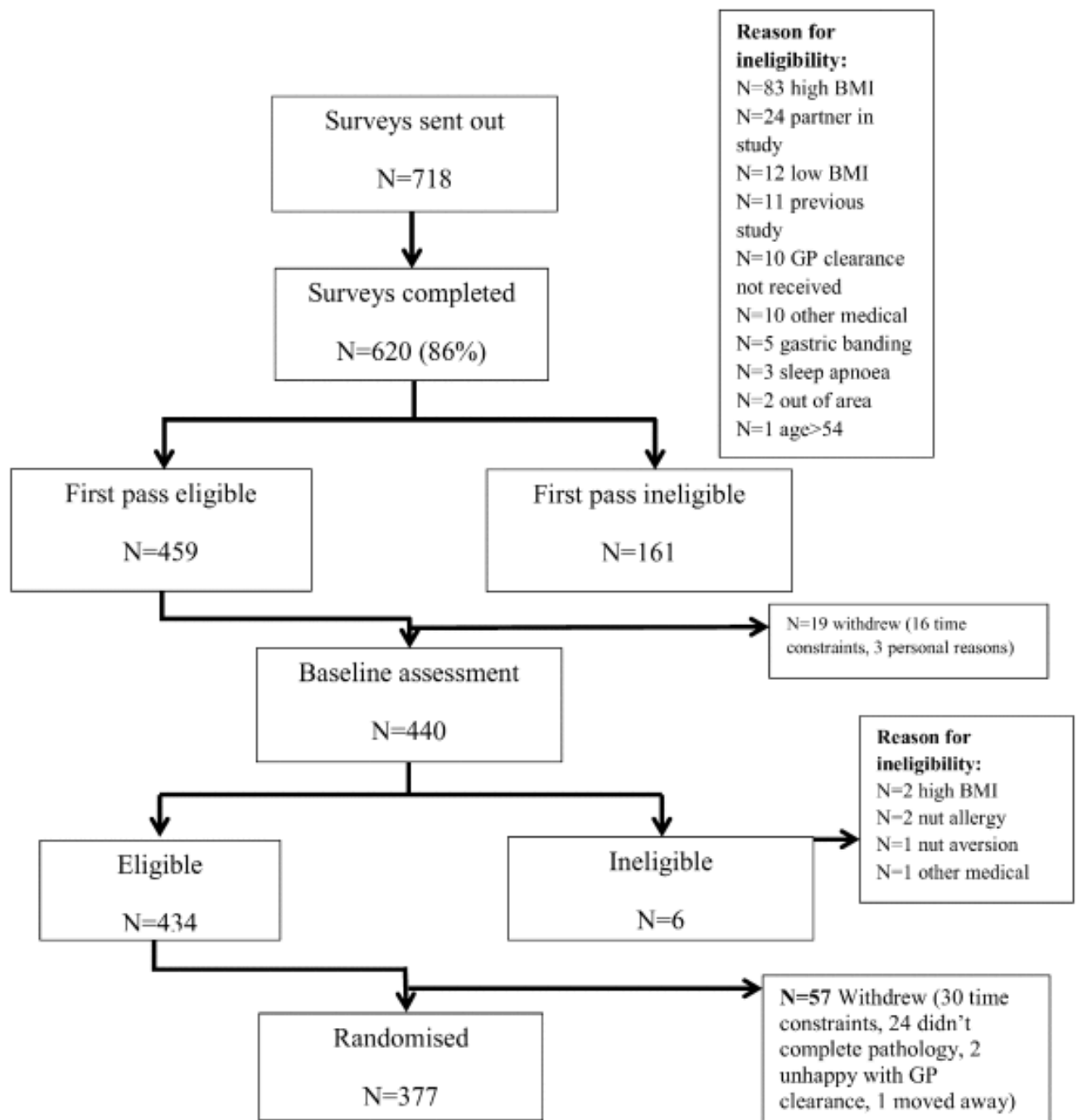
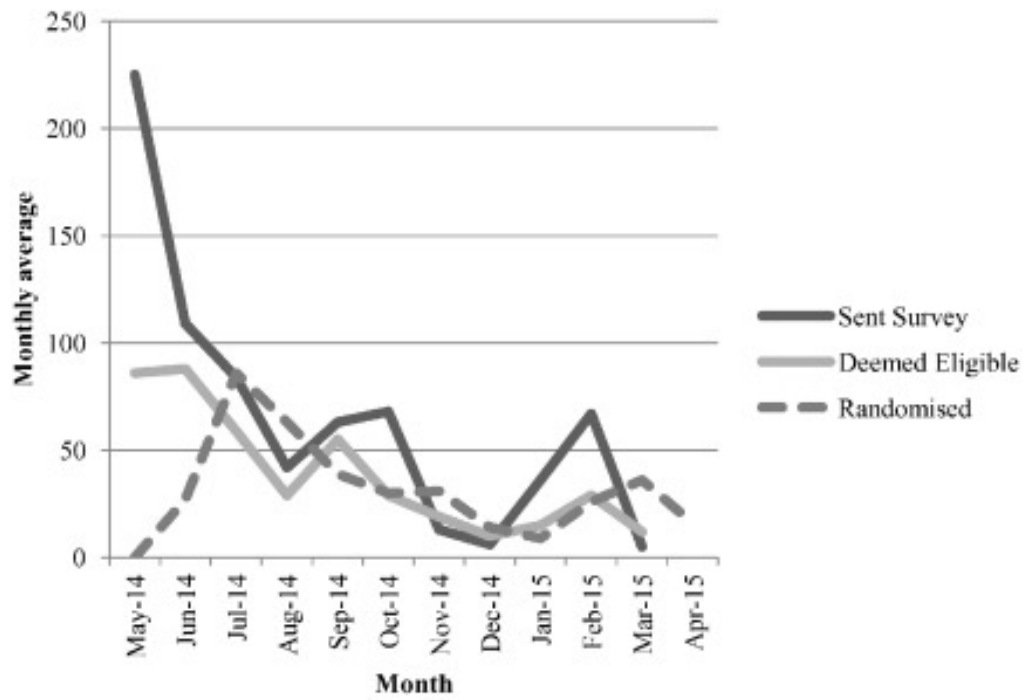


Fig. 2.

HealthTrack study recruitment flow chart.



	Sent Survey	Deemed Eligible	Randomised
Monthly Average (overall)	65	39	34

Fig. 3.

Timeline of recruitment process.