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Contemporary Clinical Trials

The Logan Healthy Living Program: A cluster randomized trial of a telephone-delivered physical activity and dietary behavior intervention for primary care patients with type 2 diabetes or hypertension from a socially disadvantaged community - rationale, design and recruitment

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ABSTRACT

Background: Physical activity and dietary behavior changes are important to both the primary prevention and secondary management of the majority of our most prevalent chronic conditions (i.e., cardiovascular disease, hypertension, type 2 diabetes, breast and colon cancer). With over 85% of Australian adults visiting a general practitioner each year, the general practice setting has enormous potential to facilitate wide scale delivery of health behaviour interventions. However, there are also many barriers to delivery in such settings, including lack of time, training, resources and remuneration. Thus there is an important need to evaluate other feasible and effective means of delivering evidence-based physical activity and dietary behaviour programs to patients in primary care, including telephone counseling interventions.

Methods: Using a cluster randomized design with practice as the unit of randomization, this study evaluated a telephone-delivered intervention for physical activity and dietary change targeting patients with chronic conditions (type 2 diabetes or hypertension) recruited from primary care practices in a socially disadvantaged community in Queensland, Australia. Ten practices were randomly assigned to the telephone intervention or to usual care, and 434 patients were recruited. Patients in intervention practices received a workbook and 18 calls over 12 months. Assessment at baseline, 4-, 12- and 18-months allows for assessment of initial change and maintenance of primary outcomes (physical activity and dietary behavior change) and secondary outcomes (quality of life, cost-effectiveness, support for health behavior change).

Conclusions: This effectiveness trial adds to the currently limited number of telephone-delivered intervention studies targeting *both* physical activity and dietary change. It also addresses some of the shortcomings of previous trials by targeting patients from a disadvantaged community, and by including detailed reporting on participant

representativeness, intervention implementation and cost-effectiveness, as well as an evaluation of maintenance of health behavior change.

Keywords/Phrases: Health behaviour interventions; Telephone counselling; Chronic disease self-management; Secondary prevention

1 INTRODUCTION

Physical activity and dietary behavior changes are important to both the primary prevention and secondary management of the majority of our most prevalent chronic conditions (i.e., cardiovascular disease, hypertension, type 2 diabetes, breast and colon cancer) [1]. Together they account for 10% of the overall disease burden in Australia [2], and 17% in the U.S [3]. The population prevalence of insufficient physical activity and inadequate diet is high among adults in economically developed countries [4-6], with the majority of the population failing to meet even minimal level recommendations for physical activity and healthy eating. Levels of these behaviors are even lower among socioeconomically disadvantaged subgroups, who bear an excess burden of disease [7,8]. This, combined with epidemic rates of lifestyle-related diseases and high rates of overweight and obesity, underline the imperative to develop population-based approaches to address these key health behaviors, especially among disadvantaged subgroups.

There is now a very large evidence base documenting the efficacy of physical activity and dietary behavior interventions for adults. These have been evaluated across a range of settings (e.g., primary care, worksites, community centers) and target populations (both healthy and chronic disease groups), and utilizing a range of intervention modalities (e.g., face-to-face sessions, telephone counseling, tailored print materials, the Internet and email) [9-12]. Many of these delivery modalities, including mailed print materials, telephone-delivered, computer-tailored, and Internet-delivered interventions have the potential for wide population reach. Telephone-delivered health behavior interventions also have the potential for being adopted by the growing number of government and non-governmental agencies and health maintenance organizations that operate telephone information, support and triage centers [13].

We recently completed a systematic review of telephone interventions for physical activity and/or dietary change [14]. Twenty of the 26 studies reviewed reported significant behavioral improvements. Factors associated with positive outcomes were the length of intervention and the number of calls, with interventions lasting six to 12 months and those including 12 or more calls producing the most favorable outcomes. However, gaps remain in this literature, including the need for studies evaluating: multiple health behavior change interventions; intervention outcomes with socially disadvantaged subgroups; the fidelity and costs of intervention implementation; and the maintenance of health behavior change.

The Logan Healthy Living Program is a trial of a telephone-delivered intervention for physical activity and dietary change targeting patients with chronic conditions (type 2 diabetes or hypertension) recruited from primary care practices in a low-income community in Queensland, Australia. With over 85% of Australian adults receiving primary medical care each year, the general practice setting offers significant advantages for population-based delivery of health behaviour interventions[15]. Reviews of the literature on primary care-based health behavior interventions suggest that this is an intervention setting in which both large and representative samples can be reached [16,17]. Although there is good evidence for the efficacy of such programs [16,18], their uptake has been modest [19]. Our recent review of general practitioner (GP) barriers to physical activity counseling[18], indicates that lack of time, lack of training, and lack of reimbursement remain significant barriers to widespread adoption in primary care. Thus we need to evaluate other feasible and effective means of delivering evidence-based physical activity and dietary behaviour programs to patients in primary care, such as referral to a telephone counseling intervention.

This trial adds to the currently limited number of telephone-delivered intervention studies targeting *both* physical activity and dietary change. It also addresses some of the shortcomings of other trials by targeting patients from a socially disadvantaged community, including detailed reporting on participant representativeness, intervention implementation and cost-effectiveness, and evaluating the maintenance of health behavior change. This paper describes the study methods and presents data on the recruitment and representativeness of practices and patients. The discussion highlights the recruitment challenges and the trade-offs between realistic field conditions and experimental control in the context of this effectiveness trial.

2 METHODS

2.1 Study Design and Aims

The aim of this trial is to evaluate a 12-month telephone and print-delivered physical activity and diet intervention compared to usual care, for patients with type 2 diabetes or hypertension recruited from the general practice setting in a socially disadvantaged community. A cluster-randomized design was used, with general practice as the unit of randomisation (cluster) and patients as the unit of analysis. Cluster randomization was used to control for potential contamination that could arise from having both intervention and usual care participants within each general practice setting. A cost-effectiveness analysis of the intervention compared to usual care will also be conducted, the methodology for which has been described elsewhere [20].

Ethical approval was granted from The University of Queensland Behavioural and Social Sciences Ethical Review Committee. All individuals provided informed consent prior to participation in the trial. Patient recruitment took place from February 2005 through October 2006.

2.2 Setting

Patients were recruited from general practices serving a community with significant socioeconomic disadvantage. The Logan area (population 220,000) is a large and ethnically and socioeconomically diverse community in Queensland, Australia, which sits on the outskirts of Brisbane, the state capital and an urban center of 1.5 million residents. Logan has significantly elevated indicators of social disadvantage compared to the rest of Brisbane and Queensland, including a greater percentage of single-parent families, unemployment and residents born overseas [21].

2.3 Practice Sampling and Recruitment

General practices were recruited from the Logan Area Division of General Practice (LADGP), a state and federally funded organization that provides administrative, technical and professional development/educational support to local area practices. At the time of commencement of the study, the LADGP supported 84 practices, with 267 GPs. The study aimed to recruit 10 practices over two years, with an attempt to recruit practices from the areas of greatest socioeconomic disadvantage within the Logan community. To do this, general practices within the LADGP were ranked by index of relative socioeconomic disadvantage (IRSD)[22]. Practices in rank order from lowest IRSD (i.e, most disadvantaged) were approached until the required sample of 10 practices agreed to participate. Practices were initially contacted by telephone to determine whether electronic medical records could

be used to perform patient searches by medical condition, and whether 150 potential participants could be identified. Eligible practices were sent an invitation letter and study brochure. This was followed-up by a phone call from a GP working within the LADGP (author KW), and a practice visit from the project manager to solicit consent.

2.4 Patient Sampling and Recruitment

Within practices, electronic medical records were searched for potentially eligible patients. Eligibility was based on: diagnosis of type 2 diabetes or hypertension; age 30 years or older; and having a telephone number. The lists of potentially eligible participants were initially screened by treating GPs for contraindications to participation. The following contraindications, used in a previous trial from which our intervention was adapted [23] were used to enhance the safety of the unsupervised exercise and diet intervention for middle to older adult patients with chronic medical conditions: being treated with insulin (type 2 diabetes), active heart disease, undergoing dialysis, taking warfarin, planning knee/hip replacement within next 12 months, regular use of a mobility aid, breathing problems requiring hospitalisation or oxygen use within previous 6 months.

The allocation of treatment and usual care practices was determined prior to practice recruitment by simple random allocation using a computer generated random number table. This was done to forecast recruitment and workloads of intervention delivery staff. Once practices agreed to participate, a time that suited the practice (which was sometimes delayed due to other commitments or staff turnover) was scheduled to commence patient recruitment. GPs and staff within practices were not informed of the allocation until after GPs had screened patient lists. This is consistent with CONSORT guidelines for cluster randomized trials [24] to prevent the potential for selection bias introduced by GPs.

Eligible patients, based on GP screening, received a letter from their GP informing them of the study, along with a study information sheet (specific to the allocated group for the practice) and a decline form with a return, pre-paid envelope. Using a passive consent to contact procedure, the letter from the GP informed patients that they would receive a call from project staff to further explain the study unless they returned the decline letter or contacted their GP to decline. During the ensuing phone call, a detailed explanation of the study was provided, patients were re-screened for eligibility based on the same criteria as GPs (to account for variation in GP screening) and consent to participate in the study was sought. Participants who provided verbal consent to participate were posted a consent form (and reply paid envelope) and an answer card to assist with data collection. Participants were not screened for baseline levels of physical activity and diet, and were not excluded from the study if they were already meeting national guidelines for one or both of these behaviours.

Pilot work which involved the recruitment of patients by electronic medical records from three practices within the LADGP found that 20% of patients identified from the electronic medical record were screened ineligible by the GP; 9% declined participation via the decline form; 76% of calls to those who had not returned the decline form were successful; of the successful calls 77% were eligible based on screening criteria; and 65% of those eligible consented to participate. To achieve the desired sample of 40 participants per practice approximately 150 patients needed to be identified from electronic medical records. When greater than 150 patients were identified within a given practice, these were randomly selected from the full list of potentially eligible patients. Lists per diagnosis ('index condition') were cross-checked to ensure individuals identified on both index condition lists were only counted once.

2.5 Study Groups

Table 1 provides an overview of the content of the intervention and 'usual care' groups.

Telephone Counseling Intervention

Theoretical Framework: The underlying theoretical perspective used to guide the telephone intervention derives from Social Cognitive Theory (SCT) [18] and the Social-Ecological Model [25-27]. The theory matrix in Table 2 lists the specific theoretical constructs addressed in the Logan Healthy Living Program, the way in which they were operationalized in the context of intervention delivery, the mediating factors (or aspects expected to change as a result of addressing the theoretical construct), and the outcome or process variables measured to evaluate how the intervention works [28]. Self-efficacy, or confidence in one's ability to make health behavior changes, is a key construct of SCT [29] and is addressed throughout the intervention via emphasis on setting small, measurable and achievable health behavior change goals that facilitate a sense of confidence and mastery that can be built upon throughout the intervention. As numerous other trials have demonstrated the relationship between increases in self-efficacy and improvements in health behavior change [30-33], we did not measure self-efficacy as a mediating variable, but will instead track the number and type of goals set (physical activity or diet) and will evaluate their relationship to health behavior change. Outcome expectancies, or beliefs about the benefits of health behavior change and the barriers that might get in the way, is another key construct of SCT [29]. Participants were encouraged to identify expected benefits of improvements to physical activity and diet, as well as the barriers that might hinder their progress; they were assisted in using a problem-solving approach to addressing barriers.

The Social-Ecological Model informs the emphasis on the social-environmental context in which health behavior change occurs, and in particular, on the challenges faced by the participants in this trial, many of whom come from disadvantaged neighborhoods; it also suggests the need to identify multi-level support for change (ie, from family, friends, co-workers and community) [34]. Participants were encouraged to identify supports for health behavior change, particularly in relation to maintenance (discussed below), and to develop strategies for increasing supports. Increases in multi-level support for health behavior change were measured using the Chronic Illness Resources Survey [34] (described below).

Consistent with these theoretical constructs, intervention delivery was guided by a chronic disease self-management intervention model developed in previous trials (Figure 1) [25], and by techniques of motivational interviewing. In this patient-centered intervention model, participants are guided through a series of steps, beginning with a detailed *assessment* of their current physical activity and dietary behaviors, which occurs at baseline and subsequent study assessments. They receive *feedback* on these health behaviors in relation to national recommendations; consistent with a motivational interviewing approach, this feedback also highlights the discrepancy between their health goals and their current health behaviours; they set *collaborative goals* for physical activity and dietary change with their telephone counselor, with the participant encouraged to begin with the target area in which she/he is most motivated to change; all of this is incorporated into a *behaviourally-specific Action Plan* that specifies exactly what is to be done and when; *barriers and supports* are identified; *confidence* is assessed and *problem-solving* is discussed as necessary. These steps are repeated during intervention contacts, with goals being adjusted as necessary.

Intervention Duration & Call Schedule: The intervention was delivered over 12-months with 18 telephone calls. Using an intervention schedule adapted from the work of King and colleagues to facilitate initiation and maintenance of behavior change [35,36], calls were delivered weekly for the first three weeks, then fortnightly until four months, and then monthly for the remaining eight months. Calls were intended to last approximately 20 minutes.

Intervention Targets: The intervention targeted both physical activity and healthy eating, with recommendations consistent with national guidelines for these health behaviors. Participants were able to choose which health behavior they wanted to focus on initially (physical activity or diet), and within each area, which specific aspects, as described below. Consistent with the chronic disease self-management intervention model, the choice of when or whether to move on to another target behavior was made in collaboration with the telephone counselor and used feedback from the participants' health behavior assessments. However, during the course of the 12-month intervention, participants were encouraged to work on both physical activity and dietary goals.

Physical Activity: Participants were counseled to meet (or exceed) the recommendation of 150 minutes a week of accumulated moderate activity on five or more days per week [4]. Given the middle to older age range of the study sample and their multiple chronic conditions, walking was emphasized. Stretching and strength exercises were also encouraged, consistent with guidelines for older adults [37].

Diet: Participants were encouraged to meet the Australian dietary recommendations – five servings per day of vegetables, two servings per day of fruit, < 30% of energy intake from total fat, < 10% of energy intake from saturated fat, 30grams per day fibre [38,39].

Intervention Workbook: A detailed workbook (along with a pedometer, a self-monitoring form, and a stretch band) was mailed to participants prior to the first counseling call. The workbook was adapted from the work of Demark-Wahnefried and colleagues [23]. The first section contained tailored feedback, graphically represented, comparing participants' current levels of physical activity and dietary behaviors to national recommendations. New tailored graphs were mailed to participants following each study assessment. In addition to sections on physical activity and diet, consistent with a SCT approach to health behavior change, the workbook also contained information on goal setting, problem-solving, self-rewards, social support, positive self-talk, relapse, and action plans. Telephone counselors regularly refered to the workbook during intervention calls, emphasizing the development and ongoing review of action plans.

Maintenance: A number of aspects of the intervention were designed to promote the maintenance of health behavior change. The intervention was implemented over a relatively long (12-month) period, with a 4-month intensive call phase and an 8-month maintenance phase. During the maintenance phase, increasing emphasis was placed on identification of multi-level supports for health behavior change [34,40]. Participants were encouraged to use a variety of supports including family and friends, members of their health care team, as well as neighborhood and community supports. Prior to beginning the study, and in collaboration with Logan community partners, a community reference guide was compiled that enabled

counselors to refer participants to specific community resources (eg, walking groups, weight management groups).

Intervention Design and Delivery for Participants from a Socioeconomically Disadvantaged Community: The intervention was developed with the challenging nature of Logan community sample in mind. This included: use of a telephone-delivery model that required no face-to-face contact, a protocol for repeated contact attempts to those missing scheduled calls, attention in the study workbook to overcoming low-literacy levels, and consultation with community organizations serving the various ethnic and underserved groups in Logan, that was fed into the training of study telephone counselors (see below).

Usual Care

After each assessment, usual care participants were sent a thank you letter that included very brief feedback on their assessment, indicating the areas in which they might like to focus (based on those in which they were not meeting national guidelines). Included in this mailing were standard, off-the-shelf brochures on a range of health behaviors (including diet, physical activity, smoking, alcohol and sun protection), and a project newsletter that provided updates on the number of study participants along with general health tips. This assessment and brief health behavior feedback constituted more than what usual care would normally involve. However, this was done to minimize the potential for greater attrition from patients in usual care practices, which was deemed to be significant, given the 18-month duration of the trial and the hour-long, repeated telephone assessments.

2.6 Telephone Counselor Training

The four project telephone counselors had bachelor's or master's degrees in either public health/health promotion or the allied health sciences (nutrition or exercise). Their study training took place over the course of a month and was guided by a detailed training manual which emphasized a patient-centered, motivational interviewing approach to telephone health behaviour counseling [41]. Training involved reading study materials, discussions with study investigators, viewing of motivational interviewing videotapes, and numerous roll plays. Counselors also made a number of visits to the study community to familiarize themselves with the community culture and local resources. Calls are taped on a regular basis to ensure fidelity of intervention delivery and to provide counselor feedback. Counselors also debrief with each other weekly and participate in fortnightly supervision sessions with study investigators.

2.7 Outcomes

Data from participants are collected at baseline, 4 months, 12 months and 18 months by computer-assisted telephone interview. This allows for evaluation of initiation of behavior change (4-months), end of intervention outcomes (12-months), and an assessment of maintenance of behavior change following a 6-month period of no intervention contact (18-months). Demographic data are collected at baseline only and includes age, education level, household income, employment status, marital status, ethnicity, health conditions, height and smoking history. Adverse outcomes are assessed at all follow-up assessments (4-months, 12-months, 18-months) with one item "Have you had any health problems related to participating in the program?" If the respondent answered "yes" then information was sought about the health problem.

Primary Outcomes

Physical activity is assessed using three instruments. We used a modified CHAMPS physical activity questionnaire consisting of 31-items assessing duration of participation in low, moderate and vigorous physical activities in a typical week over the past four weeks [42,43]. Modifications included deleting some low-intensity items that did not contribute to the scoring, adding additional sedentary behaviour items, and replacing the categorical response scale with a continuous one that asked respondents to report total weekly minutes of physical activity. Data are scored in terms of frequency per week and minutes per week in all physical activities and in moderate physical activities. The Active Australia survey is a 6-item measure assessing number of sessions and total time per week spent on walking, vigorous and moderate physical activities over the last seven days. Total minutes of physical activity is calculated from the sum of walking, moderate and 2 x vigorous minutes and truncated at 1680 minutes per week [4]. In addition to this continuous variable, Active Australia data are also used to determine whether participants are meeting physical activity guidelines, as follows: sufficiently active = 150 minutes or more of moderate intensity activity on 5 or more days/week; insufficiently active = 1-149 minutes of activity and/or less than 5 days/week; inactive = zero minutes of physical activity. Two items were adapted from the U.S. National Health Interview Survey [44], which assess the number of days and amount of time in the past week spent walking for exercise.

Diet is assessed using the Anti-Cancer Council of Victoria (ACCV) Food Frequency Questionnaire (FFQ) and the Dietary Behaviour Questionnaire, the latter developed specifically for this trial. The FFQ includes 74 food items with responses on a 10-point scale (1 = Never to 10 = 3 or more times per day), four pictorial questions relating to portion size and 10 cross-check questions used to adjust for overestimation and types of food products

consumed (milk, bread, spread and cheese) [45]. It was modified to ask about food intake over the previous month instead of the previous12 months and to be telephone administered instead of self-administered (participants receive a copy of the portion size pictures in the mail). Nutrient intakes are computed from FFQ responses using software developed by the ACCV based on the NUTTAB95 nutrient composition data (Australian Government Publishing Service, Canberra) and will be reported as continuous variables to compare with national dietary recommendations – percent of energy intake from total fat and saturated fat and grams of fibre.

The 22-item Dietary Behavior Questionnaire (DBQ) was developed (adapted from previous short dietary questionnaires [46-49]) to assess behaviors related to fat and fibre intake that were targeted as part of the intervention. The first two items relate to daily serveings of fruit and vegetables and have been found to be valid and reliable [48] . These two items will be reported separately while the remaining 20 items will be scored (1 to 5, with higher score indicating healthier dietary behaviour) to provide an overall dietary behaviour score as well as fat behaviour and fibre behaviour sub-scale scores.

Secondary Outcomes

Secondary outcomes include weight change, quality of life, support for health behavior change, participant satisfaction, and detailed assessment of intervention implementation. Self-reported weight is collected at baseline and follow-up assessments, and although the intervention is not targeted at weight loss, weight change is assessed as a secondary outcome. The Short-Form (SF)-36 Version 2 Health Survey is used to assess health-related quality of life across eight dimensions – physical functioning, social functioning, role limitations due to physical problems, role limitations due to emotional problems, bodily pain, vitality, general

health and mental health [50]. The SF-36 Version 2 has been adapted and validated for use in Australia [51]. Multi-level support for health behavior change is measured with the Chronic Illness Resources Survey (CIRS) [34], which is based on a social-ecological model of support resources. The CIRS was modified to include items relating only to personal, family and friends, health care providers, neighbourhood and community subscales, and excluded the items relating to media and policy and work subscales as the study did not aim to intervene on these levels of support. The CIRS is rated on a 5-point Likert scale (1 = none of the time, to 5 = all of the time) and has shown to be sensitive to intervention effects [40]. Participant satisfaction with the program is assessed at 4-month and 12-month follow-ups using brief questions developed specifically for this study.

Assessment of intervention implementation

All participant contacts are systematically tracked to allow for reporting on: the number of call attempts, completed calls (or 'dose' of intervention received), number of calls completed at the scheduled time (versus via call back), reasons for missed calls, and call duration. The call content is also tracked via checklists completed after each call allowing for reporting on the extent to which the intervention content is delivered per protocol, and the percentage of participants setting goals for physical activity, diet or both behaviours.

Cost-effectiveness

Study outcome data will be used, in conjunction with secondary data on long term mortality risks, to assess the cost-effectiveness of the intervention. A decision analytic model will be constructed. The methods used to build this model have been described elsewhere [20]. An incremental cost effectiveness ratio (ICER) for the intervention will be estimated in the usual way:

$$ICER = \frac{C_I - C_C}{E_I - E_C} = \frac{\Delta C}{\Delta E}$$

where: C_I represents economic costs after the intervention has been implemented; C_C represents economic costs for the comparator (i.e. usual care); E_I represents the level of health benefits after the intervention has been implemented; and, E_C represents the level of health benefits with the comparator. Therefore, ΔC represents the change in cost due to the intervention compared with the comparator and ΔE represents the change in health benefits due to the intervention compared with the comparator. The ratio of ΔC and ΔE is interpreted as the amount by which cost changes in order to obtain a unit of health effect and this is the incremental cost-effectiveness ratio (ICER).

Change to costs will be measured in Australian dollars and change to health benefits in quality adjusted life years (QALYs). The costs of delivering and managing the intervention will be included as will the changes in usage of health care services and travel costs and out of pocket expenditures for the participants. QALYs capture both changes to quantity and quality if of life and are the standard measure used by health economists for decision-making [52]. Decision makers in Australia tend to recommend funding programmes that generate a cost per QALY less than $40,000 [53].

General Practitioner Data

Demographic data (sex and age) were collected from participating GPs. Data for non-participating GPs were obtained from the Australian Medical Publishing Company (AMPCo) database. The IRSD for participating and non-participating general practices was obtained from the Australian Bureau of Statistics based on the 2001 Census Data.[22].

2.8 Sample size and power calculations

Effect size estimates for the proposed study are based on published results of other telephone or print-delivered physical activity and diet interventions [54-59] and take into account clinically meaningful differences. Based on the above, and designed around 90% power to detect these differences at the 5% (two-tailed) significance level, we expect to see average differences in change from baseline to 12-months follow-up between intervention and control groups of +60 minutes/week for physical activity; -3% for energy from fat (absolute); -1% for energy from saturated fat (absolute); +1 serving of fruit; +1 serving of vegetables; and +5 grams of fibre. To detect a mean difference of 60 minutes in physical activity between the intervention and control group with 90% power and 5% significance (two-tailed), assuming a standard deviation of change of 121.5 minutes [60] requires 103 participants per group. As this is a cluster-randomised trial, sample size calculations and analyses need to consider clustering effects (similarities between participants in the same practice compared to across practices). Our initial pilot work estimated the intracluster correlation (ρ) by GP practice for physical activity minutes to be 0.006; with an average cluster size of 40 this leads to a design effect (inflation factor) of 1.23. Assuming a non-differential attrition rate of 20% that means 165 subjects per group are required. Similarly, to detect a mean difference of 1 serving of vegetables between the intervention and control group with similar power and significance, assuming a standard deviation of change of 2.4 servings [60], design effect of 1.39 ($\rho = 0.01$) and 20% attrition, 202 participants per group are required. Therefore, to assess all outcomes with sufficient power a minimum sample size of 200 per group is required, resulting in 40 participants from each of the 10 practices.

2.9 Statistical Analysis

Randomisation optimizes our chances of similarity between intervention and usual care groups for baseline characteristics. However, any characteristics that differ substantially between the two groups at baseline will be adjusted for in all multivariable models. Analyses of primary outcomes are carried out on an intention-to-treat basis, to determine whether there are differences in changes in physical activity and dietary intake between intervention and usual care groups. Potential confounders, main effects of group and time, and the interaction of group by time effects are included in repeated measures analysis regression models. A generalised estimating equations (GEE) approach is used (SUDAAN statistical package, Version 8.0.2, 2003, NC, USA) and baseline values are included as a covariate to reduce the residual standard error and account for regression to the mean effects. The GEE approach is able to include all available data for each individual and also allows for the clustering by GP practice in the estimation of standard errors. Adjusted mean changes in each outcome for intervention and control will be reported along with associated 95% confidence intervals. Interpretation of results is balanced between effect size (intervention effect achieves levels consistent with the *a priori* contextually important difference defined earlier) and statistical significance, acknowledging that even within the primary outcomes, we may be over-powered for some and under-powered for others, depending on recruitment goals and their attainment.

3 RESULTS

3.1 General Practice (Cluster) Recruitment

Figure 2 shows the process of practice (cluster) recruitment. Of a total of 84 practices in the geographic area, 47 practices were approached, of which 11 were ineligible (9 had no or insufficient electronic medical records, 2 were not able to identify at least 200 patients). From the 36 eligible practices, we were able to recruit the 10 needed for this trial (27.8% recruitment rate). Across participating practices, 88.7% (range 20 – 100% within practices) of GPs agreed to participate, with a total of 25 GPs agreeing for their patients to be approached about the study.

Table 3 shows the baseline characteristics of participating (n = 10) and non-participating (n = 26) general practices and practitioners within those practices. At the practice level, the number of GPs within the practice did not differ between participating and non-participating practices or intervention and usual care practices. The IRSD of non-participating practices was lower than participating practices, indicating that non-participating practices were from areas of lower socioeconomic status. The mean IRSD of practices that were ineligible (due to not having electronic medical records) (856 ± 57) was similar to that for eligible practices (both participating and non-participating) (mean IRSD = 897 ± 72). The IRSD of intervention and usual care practices was not different. At the GP level, participating and non-participating GPs did not differ with respect to sex or age. Intervention and usual care GPs also did not differ on these characteristics.

3.2 Participant Recruitment

Figure 3 shows the flow of participants through the recruitment phase of the study. Two thousand one hundred and seventy-two patients were identified from electronic medical records (899 from intervention practices, 1273 from usual care practices) of whom, 1319 patients were screened eligible by their GP and were sent a study recruitment letter. Overall,

72.6% of those able to be contacted and screened as eligible consented to participate in the study. As this is a cluster randomised trial, information sheets sent to participants were different for intervention and usual care practices. Thus there were two stages in the recruitment process where the group (intervention or usual care) may have impacted on recruitment – declining via initial letter and declining after having been re-screened as eligible. Slightly more patients from intervention practices declined via the initial letter (23.9%) compared to usual care practices (19.2%). A similar difference was observed for declining once eligible – 29.2% for intervention compared to 25.4% for usual care.

Data on age, sex and index condition were available from the electronic medical records for all eligible non-participants and outright refusals (those who declined via the initial letter). On declining participation, non-participants were asked to complete a brief demographic and health interview whilst on the telephone. Seventy-eight (47.6%) of the eligible non-participants agreed to complete the interview. Table 4 shows the characteristics of participants, eligible non-participants and outright refusals. There was no significant difference between participants and outright refusals for intervention group, sex or index condition. Outright refusals were significantly older. Participants and non-participants did not differ with respect to index condition or age, but participants were more likely to be female than eligible non-participants. Considerably more females, patients with hypertension and those aged between 45 – 74 years were identified from the electronic medical records and hence consented to participate in the study.

There were significant differences between participants and eligible non-participants for highest level of education, employment status, household income, marital status, body mass index category, number of chronic conditions, smoking status and fruit intake. That is,

participants were more likely to have greater than high school education, be retired and not working full-time, have a higher household income, be widowed, be obese, have more chronic conditions, be never smokers or meet recommendations for fruit intake. Participants and non-participants did not differ with respect to physical activity level or meeting recommendations for vegetable intake.

4 DISCUSSION

With strong evidence supporting the use of the telephone to deliver health behavior change interventions [11], there is now an important need for research which will inform the wider uptake and implementation of such interventions, particularly with disadvantaged or at risk groups. In response to this, the current study was designed as an effectiveness trial, conducted, as much as possible given constraints of the research, under 'real world' conditions [61]. Study methods were designed to maximise the population reach of the intervention, and with the specific goal of directing the intervention to those most in need (e.g., lower-income patients). These methods included conducting the trial in a socially disadvantaged community, recruiting participants via the primary care setting using electronic medical records searches, and not excluding participants based on their meeting national guidelines for physical activity and dietary behavior. Results of these methodologic decisions and implications for future research are discussed below.

Although we conducted the Logan Healthy Living Program trial in a socially disadvantaged community, results pertaining to the recruitment of practices and patients indicate that we

were only moderately successful in reaching those in the lowest income areas of the broader community in which the trial took place. We used the Australian Bureau of Statistics Index of Relative Socioeconomic Disadvantage (IRSD) as means of identifying practices from the lower income areas, but had difficulty recruiting practices from the lowest income areas. While the index does not lend itself to statistical comparisons, we found that non-participating practices came from areas with lower index score (i.e., greater socioeconomic disadvantage) than did participating practices. Non-participating practices provided very little information about reasons for not taking part, other than to state that they were "too busy," or "not interested." Looking at whether the requirement that practices had to have electronic medical records capability impacted upon our difficulty in recruiting practices from lower income areas revealed that this was not the case, as the mean IRSD score was similar for eligible and ineligible practices.

Despite our proactive recruitment efforts, we were only moderately successful in enrolling lower-income participants into the study. Participants had slightly higher levels of education and a higher household income when compared to eligible non-participants, with about 30% of participants with household incomes of less than $500 per week. Here too, participants' stated reasons for declining participation shed little light on this issue. Research on efforts to recruit lower income (often ethnic minority) research participants into primary care-based trials suggests that to reach the most disadvantaged, other intervention avenues may need to be incorporated, including conducting aspects of the intervention in community settings outside of primary care [62,63].

Other than the issue of income, our recruitment results indicate that we were successful in targeting the intervention to those arguably most in need, as study participants were more

likely to be obese and have more chronic conditions. This suggests that the appeal of this type of intervention may be greatest among those with a greater number of health conditions requiring lifestyle change. It is also consistent with previous research which has shown that primary care physicians are more likely to give lifestyle advice to those with chronic conditions and those who typically make more physician office visits [18,64].

Potential study participants were identified from electronic medical records, as opposed to GP referral. Previous research on primary care-based health behavior interventions has found this method of patient identification to facilitate the ability to recruit both large numbers of patients and reasonably representative samples [16,17]. This is likely because it doesn't rely on busy GPs or practice staff to remember to recruit patients, and also removes the potential for selection that might be introduced by GP or practice staff recruitment. A passive consent to contact procedure was also used, in which all potentially eligible patients were contacted about the study unless they returned a postcard to the practice declining such contact. These two recruitment procedures resulted in nearly three-quarters of patients reached and eligible agreeing to take part in the study. While patient privacy laws are making the passive consent procedure less feasible [65], results from this study suggest that it was an important part of reaching a large and fairly representative sample of a patient population that bears a high burden of disease. We did not directly compare passive to active consent procedures in this trial, however, our previous pilot work with this same study population suggested that an active consent to contact procedure resulted in less than a 40% participation rate (unpublished data).

Regarding patient exclusion criteria, we made the explicit decision not to exclude those, who, at baseline, were already meeting national guidelines for physical activity and dietary intake.

While this may ultimately impact upon intervention effect sizes, making it more difficult to achieve statistically significant study outcomes, we felt it was more consistent with the context of this effectiveness trial and the way the intervention would be delivered in the context of usual care (in which it would likely be offered broadly to patients with chronic conditions without detailed screening procedures). We also felt that patients meeting health behavior guidelines upon study entry would still derive health benefit from further improvements to physical activity and dietary intake.

This report on the study methods and recruitment outcomes from the Logan Healthy Living Program highlights the challenges associated with recruiting lower-income participants into primary care-based health behavior intervention trials, and the trade-offs inherent in conducting effectiveness trials in field settings. Future results from this cluster-randomised controlled trial will add to a growing literature on telephone and print-delivered interventions. Our results will speak to the ability of such interventions to achieve increased and *sustained* physical activity levels and improved dietary behavior in patients with multiple chronic conditions recruited from the general practice setting in a socially disadvantaged community. An important contribution of this study will be the ability to report on the feasibility and costs associated with implementing the telephone intervention, issues important in informing translation into practice. Twelve-month data collection will be complete by the end of 2007, with primary outcome results available by mid-2008.

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Table 1: Content of telephone counselling intervention and usual care groups

	Telephone Counselling Intervention	Usual Care
	Baseline Assessment	
	Program kit including graphical feedback on diet and physical activity levels	Letter with simple feedback, program newsletter, standard off-shelf brochures
Month 1	Weekly telephone calls for 1st three weeks	
Months 2 – 4	Fortnightly telephone calls	
	4-Month Assessment	
Months 5 - 12	Mailed feedback (graphs)	Letter with simple feedback, program newsletter, standard off-shelf brochures
	Monthly calls	Program newsletter, standard off-shelf brochures (at month 8)
	12-Month Assessment	
Month 12 (end of intervention)	Mailed feedback (graphs)	Letter with simple feedback, program newsletter, standard off-shelf brochures
Month 18	*18-Month Assessment*	

Table 2: Theory Matrix

Theoretical Construct	Operationalization	Mediating Factor	Outcome
SCT: Self-efficacy	Coaching in realistic and measurable goal setting	Increased self-efficacy	Number and type of goals set
SCT: Outcome expectancies	Discussion of benefits of and barriers to health behavior change	Increased benefits	Not measured
		Decreased barriers	Not measured
	Discussion of problem-solving approach to addressing behaviors	Improved ability to address barriers	Not measured
SEM: Multi-level support for health behavior change	Identification of supports for maintenance of health behavior change	Increased multilevel support for health behavior change	Chronic Illness Resources Survey
	Setting goals regarding using supports		

SCT, Social-Cognitive Theory; SEM, Social-Ecological Model

Table 3 Baseline characteristics of general practices *(clusters)* and general practitioners within practices

	Non-Participating	Participating		
		All	Intervention	Control
Practice Level				
n	26	10	5	5
No. Drs per practice				
1	6 (23.1)	1 (10.0)	1 (20.0)	0 (0.0)
2-3	12 (46.2)	6 (60.0)	3 (60.0)	3 (60.0)
4 or more	8 (30.8)	3 (30.0)	1 (20.0)	2 (40.0)
IRSD	883 ± 65	933 ± 82	921 ± 88	945 ± 85
GP level				
n	79[a]	25	9	16
% Male	77.2	64.0	55.6	68.8
Age[b]	49 ± 9	46 ± 9	50 ± 6	44 ± 11

IRSD, Index Relative Socioeconomic Disadvantage

Data are n (%) or mean ± sd

[a] includes non-participating practitioners from participating practices

[b] missing data – non-participating (n = 71), all participating (n=20), intervention (n=8), usual care (n=12)

Table 4 Characteristics of participants and non-participants

	Participants	Eligible Non-participants	Outright Refusals[a]
n	434	164	285
Group			
Intervention	228 (52.5)	94 (57.3)	162 (56.8)
Control	206 (47.5)	70 (42.7)	123 (43.2)
Data from electronic medical records			
Age			
30 – 44 years	58 (13.4)	24 (14.6)	16 (5.6)
45 – 59 years	175 (40.3)	76 (46.3)	82 (28.8)
60 – 74 years	159 (36.6)	46 (28.0)	132 (46.3)
75 years and over	42 (9.7)	18 (11.0)	55 (19.3)
Sex			
Females	267 (61.5)	86 (52.4)	165 (57.9)
Males	167 (38.5)	78 (47.6)	120 (42.1)
Index condition[b]			
Hypertension	290 (66.8)	107 (65.2)	187 (65.6)
Type 2 diabetes	144 (33.2)	57 (34.8)	98 (34.4)
Self-report data from telephone interviews[c]			
Education			
Primary or less	88 (20.3)	17 (22.1)	
Junior high school	151 (34.8)	25 (32.5)	
Senior high school	46 (10.6)	18 (23.4)	
Trade or technical diploma	99 (22.8)	10 (13.0)	

University degree	50 (11.5)	7 (9.1)
Employment		
Full time	133 (30.6)	31 (40.3)
Part time/Casual	71 (16.4)	14 (18.2)
Retired	157 (36.2)	23 (29.9)
Home Duties	38 (8.8)	4 (5.2)
Unable to work, unemployed or student	34 (7.8)	5 (6.5)
Household income (per week)		
$200 - $299	45 (10.4)	17 (22.1)
$300 - $499	85 (19.6)	12 (15.6)
$500 - $999	82 (18.9)	19 (24.7)
$1000 - $1499	85 (19.6)	8 (10.4)
≥ $1500	75 (17.3)	3 (3.9)
Do not know	54 (12.4)	7 (9.1)
Refused to answer	8 (1.8)	11 (14.3)
Ethnicity		
Caucasian	395 (91.0)	67 (85.9)
Other	39 (9.0)	11 (14.1)
Marital status		
Married	309 (71.2)	63 (82.9)
Divorced/separated	45 (10.4)	9 (11.8)
Widowed	60 (13.8)	3 (3.9)
Never married	20 (4.6)	1 (1.3)
Number of chronic conditions		

1 – 2	175 (40.6)	42 (56.0)
3 - 4	189 (43.5)	24 (32.0)
5 or more	70 (16.1)	9 (12.0)
BMI (kg/m^2)		
< 18.5	3 (0.7)	0 (0.0)
18.5 – 24.9	67 (15.4)	23 (31.1)
25.0 – 29.9	159 (36.6)	25 (33.8)
≥ 30.0	205 (47.2)	26 (35.1)
Smoking status		
Current smoker	60 (13.8)	18 (23.4)
Ex-smoker	176 (40.6)	59 (76.6)
Never smoker	198 (45.6)	0 (0.0)
Physical activity level[d]		
Sufficiently active	110 (25.3)	17 (22.4)
Insufficiently active	151 (34.8)	28 (36.8)
Inactive	173 (39.9)	31 (40.8)
Vegetable intake		
≥ 5 serves	72 (16.6)	9 (11.5)
< 5 serves	362 (83.4)	69 (88.5)
Fruit intake		
≥ 2 serves	207 (47.7)	29 (38.7)
< 2 serves	227 (52.3)	46 (61.3)

[a] Declined via the initial letter

[b] Condition under which patient was searched in the electronic medical records

[c] Eligible non-participants, n = 74 to 78

[d] Sufficiently active = 150 minutes or more of moderate intensity activity on 5 or more days/week; Insufficiently active = 1-149 minutes of activity and/or less than 5 days/week; Inactive = zero minutes of physical activity.

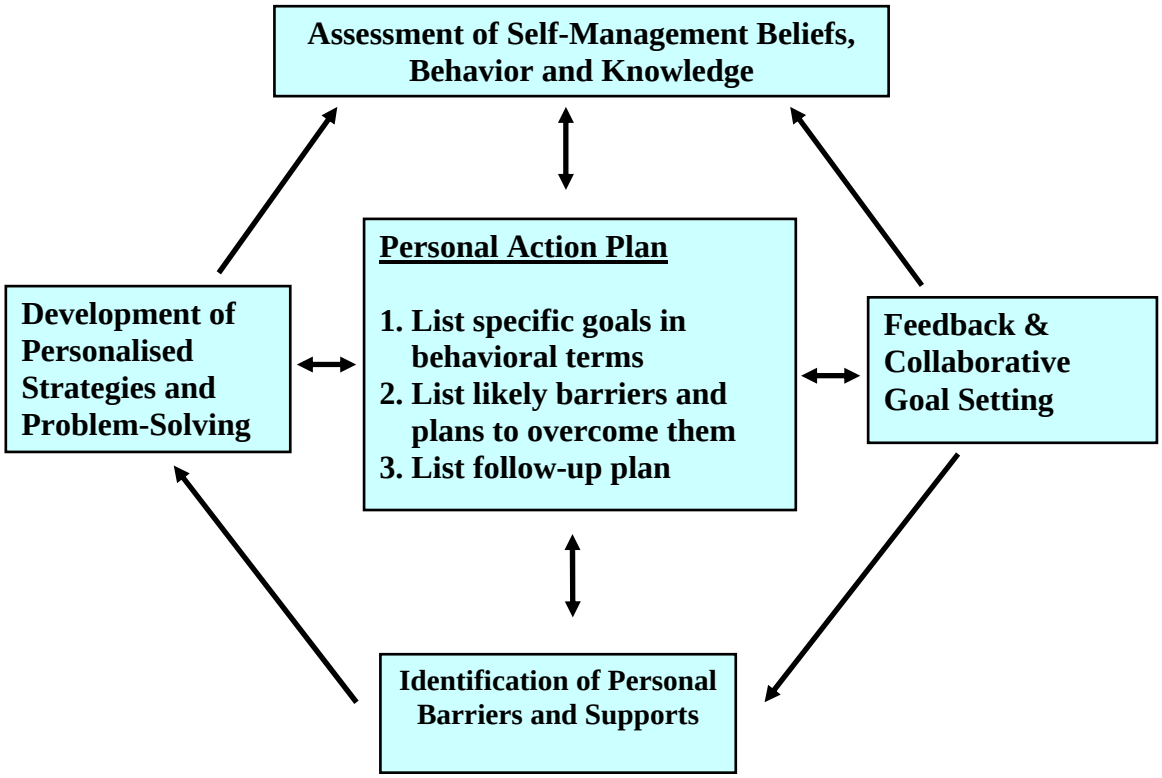

Figure 1 Chronic Disease Self-Management Intervention Model

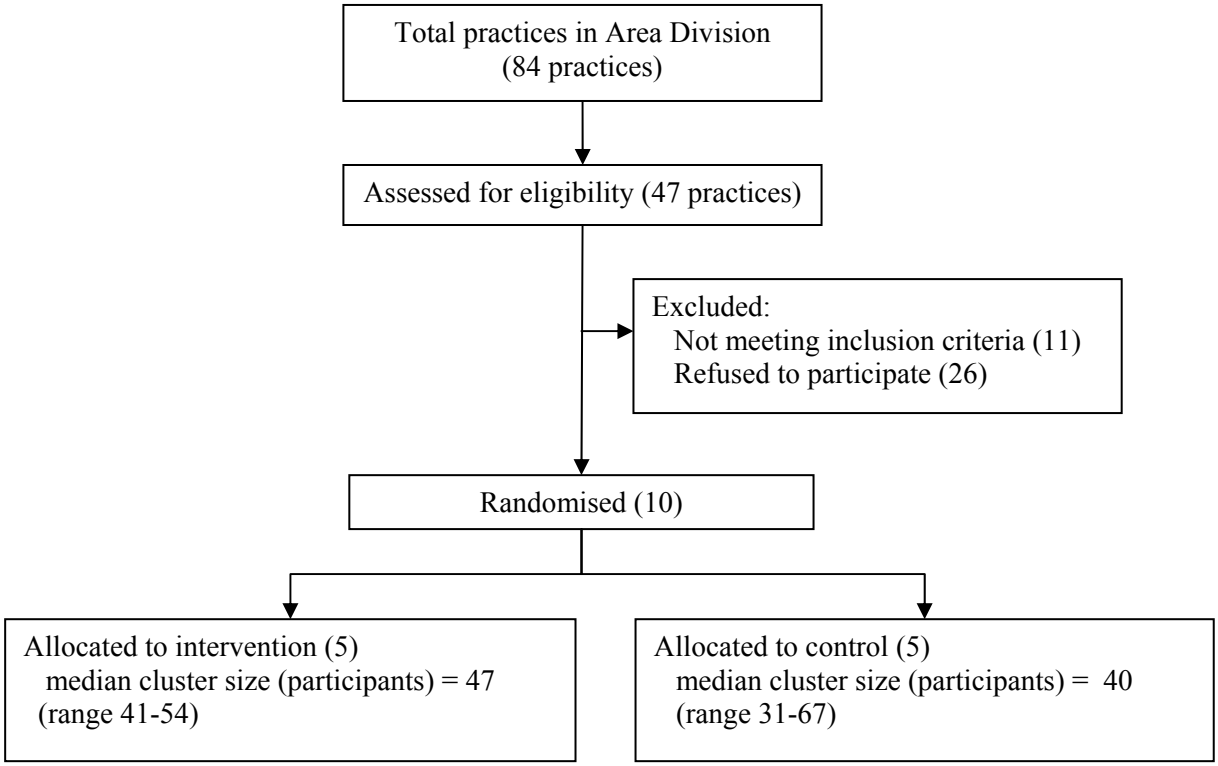

Figure 2 Recruitment of clusters (General Practices)

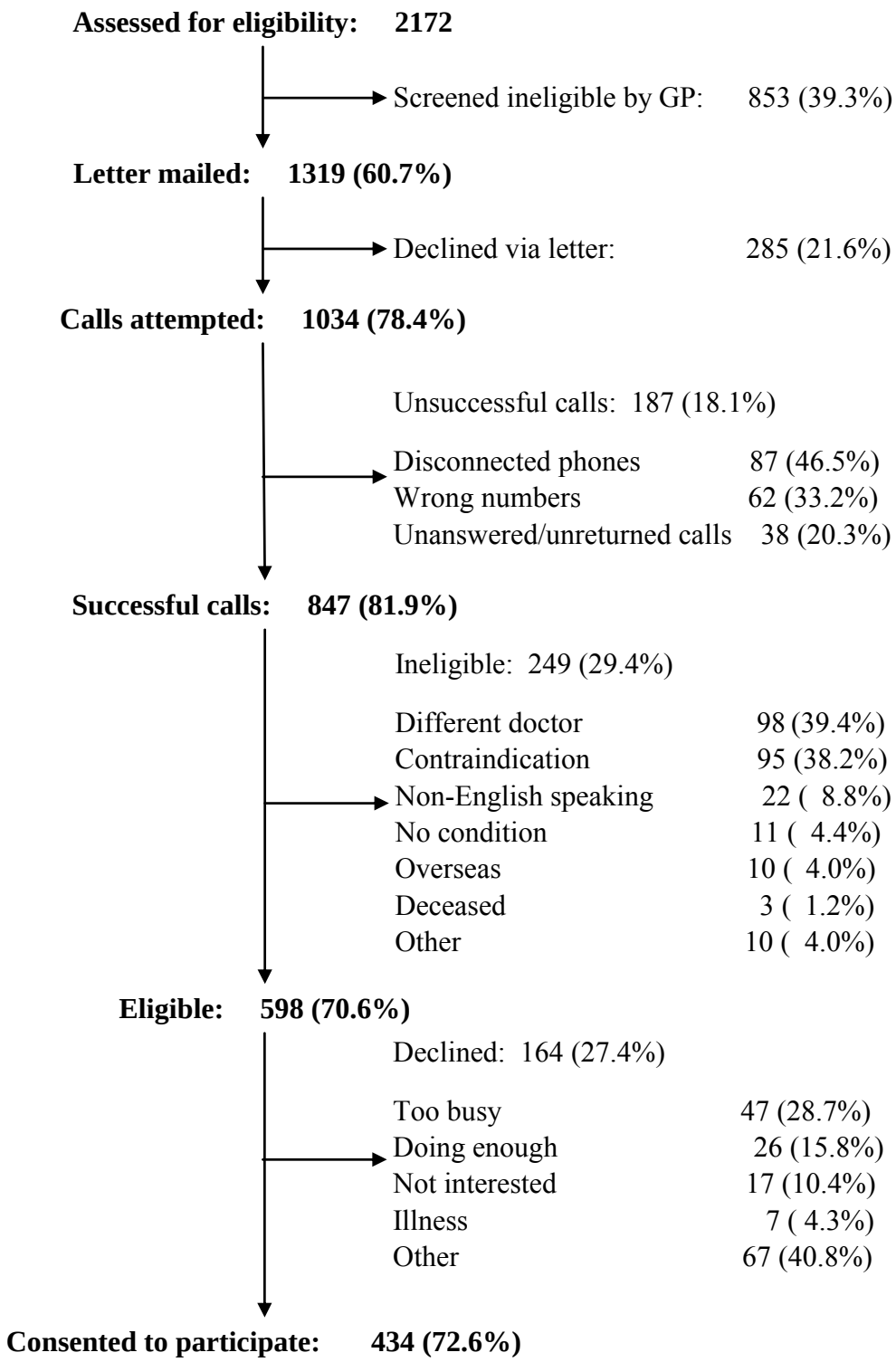

Figure 3 Participant recruitment