

Moderators of Health Behavior Initiation and Maintenance in a Randomized Telephone Counseling Trial

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Abstract

Objective: This study compares moderators of initiation and maintenance of health behavior changes.

Methods: Data come from a cluster-randomized, 12-month telephone counseling intervention for physical activity and diet, targeting type 2 diabetes or hypertension patients (n=434, Australia, 2005-2007). Demographic and health-related characteristics, theoretical constructs, and baseline behavioral outcomes were considered as moderators. Mixed models, adjusting for baseline values, assessed moderation of intervention effects for trial outcomes (physical activity, intakes of fat, saturated fat, fiber, fruit, vegetables) at end-of-intervention (12 months/initiation) and maintenance follow-up (18 months), and compared moderation between these periods.

Results: Social support for physical activity and baseline physical activity were significant ($p < 0.05$) moderators of physical activity at 12 months. Gender, marital status, social support for healthy eating, BMI, and number of chronic conditions were significant moderators of dietary changes at 12- and/or 18 months. Instances of moderation differing significantly between 12- and 18 months were: baseline physical activity for physical activity (initiation) and marital status for fat intake (maintenance).

Conclusions: This exploratory study showed moderation of physical activity and diet effects sometimes differed between initiation and maintenance. To identify unique moderators for initiation and/or maintenance of behavior changes, future studies need to report on and statistically test for such differences.

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Background

Considerable evidence attests to the importance of engaging in regular physical activity and following a healthy diet for the prevention and management of many chronic conditions, including type 2 diabetes, hypertension and some cancers (Chobanian et al., 2003, Sigal et al., 2006, Eyre et al., 2004). However, population prevalence estimates of these beneficial lifestyle behaviors remain low in most developed countries (Macera et al., 2005, Hillsdon et al., 2001, Armstrong et al., 2000, Pronk et al., 2004).

A large body of literature on interventions targeting physical activity and dietary behavior change shows strong support for the efficacy of such interventions in producing initial (end-of-intervention) improvements in physical activity, diet and related disease management outcomes in a wide range of primary and secondary prevention contexts (Goldstein et al., 2004, Vanwormer et al., 2006, Pignone et al., 2003, Goode et al., 2012). There is considerably less reporting of maintenance (the sustainability of outcomes following a period of no intervention contact) of these behavioral improvements, however when it is reported, the ability to achieve maintenance appears to be modest to good (Fjeldsoe et al., 2011, Goode et al., 2012, Spark et al., 2013), depending upon how maintenance is defined.

Limited evidence exists to elucidate which participant characteristics moderate initiation of physical activity and dietary behavior changes, and even less that examines moderators of maintenance of behavior change (Fjeldsoe et al., 2011). Such evidence is important to informing the subgroups for whom a given intervention works best, along with ongoing intervention development and refinement, and subsequent translation into practice (Glasgow and Emmons, 2007). In addition, evidence that speaks specifically to whether there are different moderators of initiation versus maintenance will help to better develop interventions designed to achieve lasting health behavior change.

Few studies have examined moderators or mediators of both initiation and maintenance of changes to physical activity and diet. In one such study by Burke and colleagues, sex was found to be a moderator of initiation but not maintenance of both diet and physical activity in patients with hypertension (Burke et al., 2008). Also, in this study, baseline age, education level, blood pressure, depression, anxiety, stress, coping and social support showed no significant moderation of response at either initiation or maintenance (Burke et al., 2008). In a home-based physical activity intervention trial targeting sedentary adults, Williams and colleagues found that home access to physical activity equipment predicted adoption (initiation), but not maintenance, whereas self-efficacy and satisfaction predicted physical

activity maintenance (Williams et al., 2008). A descriptive review of 59 studies of *predictors* (not specifically moderators) of initiation and maintenance of physical activity in older adults found outcome expectancies, action planning and social support (family and friends, social modeling and social norms) predicted initiation, while coping planning and specific types of social support (sports instructors, health professionals and exercise group members) predicted maintenance (van Stralen et al., 2009). However, evidence regarding the similarities and differences between moderators of initiation and maintenance is limited by a paucity of experimental evidence, a tendency to focus on predictors (less rigorous) rather than moderators (more rigorous) and a lack of statistical testing of the differences between initiation and maintenance. A variable can be a significant predictor of intervention-group change without being a moderator, for example if it affects intervention and control changes equally.

This study aims to explore whether moderators of physical activity and dietary behavior change are different for initiation (end of intervention) and maintenance (follow-up from end of intervention). These exploratory analyses examine demographic characteristics (age, gender, marital status, income, education and employment), health-related characteristics (weight status, number of chronic illnesses), theoretical constructs (social support for physical activity and diet), and baseline behavioral outcomes (physical activity and diet) as potential moderators.

Methods

Analyses are based on data from the Logan Healthy Living Program cluster-randomized controlled trial which evaluated a 12-month telephone counseling intervention for physical activity and diet, targeting primary care patients with type 2 diabetes or hypertension from a socio-economically disadvantaged community. Ethics approval was granted by The University of Queensland Behavioral and Social Sciences Ethics Committee. Data were collected from February 2005 to November 2007, with the present analysis conducted from September 2012 – April 2013. The rationale, outcomes and cost-effectiveness of this program have been previously reported (Graves et al., 2009, Eakin et al., 2008, Eakin et al., 2009). Main findings from the LHLP at end of intervention (Eakin et al., 2009) showed statistically significant differences in all diet outcomes and no statistically significant difference between telephone counseling and usual care groups in moderate to vigorous physical activity duration or frequency. These results were all maintained at near equal magnitude at the maintenance follow-up, except that the intervention effect for vegetable intake became only borderline

significant ($p=0.051$) (Eakin et al., 2010). Other than saturated fat, intervention effects were slightly smaller than the clinically relevant magnitudes, defined a priori for the trial (Eakin et al., 2008) as: 60 minutes per week of moderate to vigorous physical activity, one serving per day for fruit and for vegetables, 3% of energy from total fat and 1% of energy from saturated fat. Detailed methods are published elsewhere (Eakin et al., 2008), but are presented here briefly.

Participant Recruitment

Ten primary care clinics consented to participate (28% of those approached and eligible) and were randomly assigned by simple random allocation to either the telephone counseling intervention (TC) or to usual care (UC) conditions (Eakin et al., 2008). Within practices, electronic medical records were searched for patients with type 2 diabetes or hypertension. General practitioners (GPs) screened patient lists for contraindications to participation in an unsupervised physical activity and diet intervention (Eakin et al., 2008). Screened patients were sent a recruitment letter (with a reply paid decline form if they did not want to be contacted about the study), followed by a phone call from study staff, in which eligibility was confirmed and consent was solicited. Of the 2,172 patients identified, 1,319 were sent a letter of invitation from their GP (60.7%), 847 were successfully contacted by phone (64.2% of those posted a letter) and 598 were deemed eligible (70.6% of those contacted by phone). Of those eligible, 434 (72.6%) consented to participate (20.0% of original sample identified from electronic medical records) – 228 from telephone counseling (TC) practices and 206 from usual care (UC) practices.

Study Groups

Participants in the TC group were mailed a detailed workbook with information on physical activity and healthy eating, along with a pedometer. They received 18 phone calls over 12-months, tapered from weekly to bi-weekly for the first four months then monthly for the remaining eight months. The advice on physical activity and diet was consistent with Australian national guidelines: 150 minutes/week over five or more sessions of moderate-level physical activity (Department of Health and Aged Care, 1999); 5 servings/day of vegetables, 2 servings/day of fruit, less than 30% and 10% of calories from total fat and saturated fat, respectively, and 30grams of fiber/day (Australian Government Department of Health and Ageing et al., 2006). The intervention was underpinned by Social Cognitive Theory (Bandura, 1986), with an emphasis on building self-efficacy via setting achievable goals, and by the Social Ecological Model (Green et al., 1996, Sorensen et al., 2003, Stokols,

1992), with an emphasis on identification of a range of sources of support for health behavior change (i.e., family, friends, health care provider, community). Participants in the UC group received brief written feedback following each assessment, (e.g., based on what you told us you could benefit by eating more foods that are high in fiber) and received quarterly project newsletters, along with off-the-shelf brochures on a variety of health topics (including physical activity and diet).

Data Collection

Data were collected by computer-assisted telephone interviews at baseline, 4-months, 12-months and 18-months, by research staff blinded to study allocation. For the purposes of these research questions data collected at 4-months were not used in the analyses.

Primary Outcome Variables. Moderate to vigorous physical activity was measured using the Active Australia Survey. This survey has acceptable validity for the adult Australian population (Timperio et al., 2003, Fjeldsoe et al., 2013), with test-retest reliability similar to the International Physical Activity Questionnaire and U.S. Behavioral Risk Factor Surveillance Survey (Brown et al., 2004, Fjeldsoe et al., 2013). Fruit and vegetable intake were measured using two questions from the Australian National Nutrition Survey (Rutishauser et al., 2001), which have good validity against biomarkers including serum carotenoids and red-cell folate (Coyne et al., 2005). Total fat, saturated fat and fiber intake were measured using the Anti-Cancer Council of Victoria Food Frequency Questionnaire (Hodge et al., 2000, Ireland et al., 1994), which estimates most nutrients accurately (within 10%) and does not systematically under- or over-estimate against weighed food records (Hodge et al., 2000). Fat and saturated fat intakes were examined as percentage of total energy intake.

Potential moderators. Demographic characteristics were considered as potential moderators: age (60+ years, yes/no), gender, marital status (married or defacto, yes/no), income (\$1000+/week, yes/no), education (at least senior high school, yes /no) and employment (paid employment, yes/no). Health-related characteristics considered were weight status (normal or underweight/ overweight/ obese according to conventional body mass index (BMI) classifications (National Institutes of Health et al., 2000)) and number of chronic illnesses (≥ 3 / < 3). The Chronic Illness Resource Survey (CIRS) was used to measure baseline social support for physical activity and for healthy eating (Glasgow et al., 2000) respectively as moderators for physical activity and diet outcomes. The CIRS was modified to include items relating only to personal, family and friends, health care providers,

neighborhood 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. Baseline levels of the behavioral outcomes were also considered as possible moderators. In addition, physical activity was considered as a potential moderator of diet. An overall dietary quality score (Newby et al., 2003, Haines et al., 1999) was considered as a potential moderator of physical activity and dietary outcomes. These continuous variables were dichotomized at the median into high/low. Ethnicity and smoking could not be considered as moderators due to the low number of non-Caucasians and smokers in the sample.

Statistical Analysis

Data analyses were conducted in STATA (version 11.1). Analyses were by linear mixed models (West et al., 2007), with random terms for participant and practice, to accommodate the repeated measures and cluster randomization. Models included outcomes at two time points, 12-months (end of intervention, initiation) and 18-months (follow-up, maintenance), and included as covariates time (12- or 18- months), group (intervention or usual care), the group by time interaction, baseline values (continuous), the moderator of interest, and interaction terms of the moderator with group, with time, and the three-way interaction (group by the moderator by time). From these models the group difference (intervention effect) observed within each level of the moderator and the two-way group by moderator interactions (i.e., the difference in intervention effects between each level of the moderator) is reported separately for end of intervention and maintenance follow-up. Also reported are the three-way interactions, which were used to test for differences in moderation between end of intervention and maintenance follow-up. Due to the large volume of results only instances with moderation at $p < 0.05$ (at either time point) are reported in the tables. Models included only participants with outcome data at end of intervention and 18-months follow-up, who were alive up to the follow-up ($n=306$ for physical activity, fruit intake and vegetable intake models; $n=300$ for fat and fiber intake models, which excluded six participants due to invalid food frequency questionnaire data). For all instances of significant moderation, results from these models were also depicted graphically.

Results

Of the 434 study participants, 341 (78.6%) completed the end of intervention assessment and 306 (70.5%) completed both end of intervention and follow-up assessments. Loss to follow-up was non-differential (71.9% Tel, 68.9% UC, $p=0.53$). Baseline demographic and

health behavior characteristics did not differ across the study groups (Eakin et al., 2009) or by study completion status (Table 1).

Physical Activity

Moderation results for physical activity are shown in Table 2. Significant ($p < 0.05$) moderation was seen only at end of intervention, specifically by social support (CIRS) for physical activity and baseline physical activity. Figure 1 (panel a) shows that greater improvements in physical activity were seen with high social support (versus low social support) among UC participants, but not among TC participants. Moderation by baseline physical activity occurred as improvements in physical activity tended to be greater within those with low baseline activity (versus high activity)—except this did not occur in the control group at end of intervention, whose physical activity changes were similar regardless of baseline physical activity (Figure 1b).

Fruit and Vegetable Intake

Table 3 shows the moderation results for fruit and vegetable intake. There were no significant moderators of intervention effects for vegetable intake at either end of intervention or maintenance.

Significant ($p < 0.05$) moderation of intervention effects for fruit intake was seen by gender at both end of intervention and maintenance, and by marital status at maintenance follow-up only. Both at end of intervention and maintenance, the moderation by gender related to control group women (but not control group men) reporting increased fruit intake, while by contrast fruit intake increases were similarly reported by both men and women in the intervention group (Figure 2a). The moderation by marital status at maintenance follow-up related both to slightly lesser improvements in fruit intake within the intervention group who were married (versus not married), and to significant control group improvements in fruit intake that were only reported by those who were married (Figure 2b).

Saturated Fat, Total Fat and Fiber Intake

Moderation results for saturated fat, total fat and fiber intake are shown in Table 4. Social support for diet was the only significant moderator of intervention effects for saturated fat intake ($p = 0.04$). The moderation arose as reduced saturated fat intake was similarly reported by the intervention group regardless of baseline support, while only controls reporting high baseline support reported reducing their intake of saturated fat (Figure 3a).

Intervention effects for total fat intake were significantly moderated at end of intervention by number of chronic conditions and at maintenance follow-up by marital status and social

support (Table 4). The moderation at end of intervention by chronic conditions was a result of more chronic conditions relating to both greater improvements within the UC group and less improvement within the TC group (Figure 3b). Similarly, the moderation by marital status occurred both due to greater control group changes for those who were married compared with those who were not and due to lesser intervention group improvements within those who were married compared with those who were not (Figure 3c). The moderation by social support arose as the intervention group showed similar improvement in fat intake regardless of baseline support while the control group only reported improved fat intake if they also reported high baseline support (Figure 3d).

BMI was the only significant moderator of intervention effects for fiber intake. Specifically, intervention effects (at maintenance) were strongest in those who were overweight, and smallest in those who were obese. This occurred as improvements in the intervention group were greatest in participants who were overweight, while no sustained improvement was seen in obese intervention participants (Figure 3e).

Differences in moderation between initiation and maintenance

The findings did not generally suggest that moderators had different effects at initiation versus maintenance, as formally tested by the three-way interaction terms. Although there were seven instances in which moderators were observed as significant only for initiation or only for maintenance, the formal test only supported that moderation differed between initiation and maintenance in two of these instances: specifically, baseline activity as a moderator of improvements in physical activity ($p=0.010$; Table 2) and marital status as a moderator of intervention effects on total fat intake ($p=0.020$; Table 4).

Discussion

To our knowledge this paper is the first to explore true moderation of both initiation and maintenance of physical activity and dietary outcomes that formally tests whether moderation differs between these time periods. Previous studies have shown that the characteristics noted as moderators or predictors are often different for studies examining initiation compared with the fewer studies examining maintenance (Williams et al., 2008, Burke et al., 2008, van Stralen et al., 2009). However, compiling separate lists of moderators that emerge as significant at initiation and maintenance may not be enough to understand which moderators are uniquely relevant for initiation or maintenance. Adding to these findings, this study provided statistical evidence that the degree of moderation was sometimes different for initiation versus maintenance of physical activity and dietary behavior changes.

Participants' demographic and health-related characteristics mostly did not act as moderators of initiation or maintenance of intervention effects. This finding suggests that the program had equitable impact on the behavioral outcomes, across participant characteristics. While instances of significant moderation were observed, there was no consistent patterning whereby the intervention appeared more successful, or was more successfully maintained, for any particular group across a majority of behavioral outcomes. For example, men showed significantly greater improvements than women in fruit intake but not in the five other outcomes. Importantly, in the context of a program conducted in a low socioeconomic area, there was very little evidence of differential effectiveness of the program according to participants' socioeconomic position in terms of income, education or employment.

Social support specific to physical activity/diet was among the most consistent moderators in this study, emerging as a significant moderator for physical activity (initiation), total fat and saturated fat (maintenance). In our study the moderation by social support did not tend to indicate that pre-existing levels of support predicted the amount of change achievable by the intervention participants. Rather, the moderation always occurred by an association between more baseline support and stronger behavioral improvements being reported by control group participants. These findings are in contrast to previous work that did not find social support moderated physical activity and diet initiation or maintenance (Burke et al., 2008) or in a review of physical activity (van Stralen et al., 2009), and may be due to the heterogeneity of intervention protocols and study methodologies more generally.

There was minimal evidence that intervention effects for dietary behaviors differed according to baseline levels of the same behaviors, but there was for physical activity. A review by van Stralen and colleagues found that baseline level of physical activity appeared to be a consistent predictor of both initiation and maintenance of physical activity in older adults (van Stralen et al., 2009). Whereas baseline physical activity was a significant moderator for initiation, but not maintenance, of physical activity in this study of adults with type 2 diabetes and hypertension.

Moderation of initiation and maintenance can operate through a number of different mechanisms. In addition to the simple possibility that the program has selective efficacy/acceptability to certain types of intervention participants, in the context of a multiple behavior intervention trial, certain types of participants may choose to focus on some behaviors in preference to others. In our trial, there was limited support for the notion of selective efficacy of the program as a whole, based on the lack of consistent moderation across different outcomes. Also, most moderators in this study did not appear to operate by

affecting amount of change within the intervention group, instead being associated with amount of change in the control group. Thus, selective efficacy of specific behavior change components of the program was also unlikely, except in the case of BMI as a moderator of intervention effects for fiber intake. In this instance, sustained changes in fiber intake were not achieved by obese intervention participants, while overweight intervention participants sustained changes and continued to improve. The fiber-related behavior change messages in the program may have been less acceptable or effective for obese participants than for overweight participants; alternatively, obese intervention participants may have selectively chosen to focus on other behaviors (e.g. increasing physical activity, reducing fat intake) at the expense of focusing on increasing fiber intake.

The fact that most moderators related to changes within the control group could reflect that certain types of control group participants are more prone to improve their physical activity or dietary behaviors without intervention (Waters et al., 2012), or it could reflect selective reporting biases, since all outcomes were self-reported, as is the case in many studies reporting on moderators. With self-monitoring as an intervention tool it is plausible that errors and biases in reporting can differ between intervention and control participants (Winkler et al., 2013). Future studies should use objective measures (e.g., physical activity monitors and dietary biomarkers) to better eliminate apparent moderators that arise purely from selective reporting biases and to improve the current understanding of the mechanisms of moderation, and how these may diverge for initiation and maintenance.

A key contribution of this paper was testing, in a trial where participants were not a highly selective group, but rather a population-representative sample (Eakin et al., 2008), both initiation and maintenance moderation and further testing whether moderation differs between initiation and maintenance. However, this is an exploratory analysis based on a trial that was powered *a-priori* for the main (intervention) effects, but not for moderation analyses, which typically require a four-fold larger sample size than to detect the main effects of the same magnitude (Leon and Heo, 2009). Consequently, corrections were not made for the multiple hypothesis testing, to avoid unrealistically inflated type II errors. This has implications for the absence of significant moderation and of differences between initiation and maintenance; larger studies are needed, powered *a-priori*, to conclusively test for differences between initiation and moderation. Limitations include that several potentially important moderators (e.g., self-efficacy) that have been highly researched (van Stralen et al., 2009, Williams et al., 2008) were not included within the already extensive assessments

required to evaluate this multiple behavior intervention and with multiple outcomes and moderators, some of the findings may have been spurious.

Conclusions/Recommendations

This telephone-delivered intervention did not appear to be comparatively less effective on the whole for certain population subgroups, and importantly, not for the types of subgroups for whom it is of high importance that the program be effective, such as those with the most chronic conditions and those of low socioeconomic position. Like other interventions, support specific to dietary behaviors and physical activity was an important moderator for both physical activity and diet. Despite the tendency for moderators to be significant for only initiation, or only maintenance, there were only limited instances where the moderation at initiation and maintenance were significantly different. To make firm conclusions regarding which characteristics are relevant as moderators of physical activity and dietary improvements, for initiation, for maintenance, or for both, more interventions need to report on moderation at initiation and especially maintenance, statistically testing for differences between these, based on objective measures where feasible. Furthermore, to expand our understanding of moderators of initiation and maintenance of diet and physical activity interventions, a comprehensive battery of evidence-based psychosocial constructs needs to be assessed.

Conflict of interest statement

The authors declare that there are no conflicts of interest.

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References

- Armstrong T, Bauman A, Davies J, 2000. Physical activity patterns of Australian adults: Results of the 1999 National Physical Activity Survey, Canberra, Australian Institute of Health and Welfare.
- Australian Government Department of Health and Ageing, National Health and Medical Research Council, New Zealand Ministry of Health, 2006. Nutrient reference values for Australia and New Zealand: Executive summary, Canberra, National Health and Medical Research Council.
- Bandura A, 1986. Social foundations of thought and action: A social cognitive theory, Englewood Cliffs, NJ, Prentice Hall.
- Brown WJ, Trost SG, Bauman A, Mummery K, Owen N, 2004. Test-retest reliability of four physical activity measures used in population surveys. *J Sci Med Sport* 7: 205-215.
- Burke V, Beilin LJ, Cutt HE, Mansour J, Mori TA, 2008. Moderators and mediators of behaviour change in a lifestyle program for treated hypertensives: A randomized controlled trial (ADAPT). *Health Educ Res* 23: 583-591.
- Chobanian AV, Bakris GL, Black HR, Cushman WC, Green LA, Izzo JL, Jr., Jones DW, Materson BJ, Oparil S, et al., 2003. The seventh report of the Joint National Committee on prevention, detection, evaluation, and treatment of high blood pressure: The JNC 7 report. *JAMA* 289: 2560-2572.
- Coyne T, Ibiebele TI, McNaughton S, Rutishauser IHE, O'Dea K, Hodge AM, McClintock C, Findlay MG, Lee A, 2005. Evaluation of brief dietary questions to estimate vegetable and fruit consumption using serum carotenoids and red-cell folate. *Public Health Nutr* 8: 298-308.
- Department of Health and Aged Care, 1999. National physical activity guidelines for Australians, Canberra, Department of Health and Aged Care.
- Eakin EG, Reeves MM, Lawler SP, Oldenburg B, Del Mar C, Wilkie K, Spencer A, Battistutta D, Graves N, 2008. 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. *Contemp Clin Trials* 29: 439-454.
- Eakin E, Reeves M, Lawler S, Graves N, Oldenburg B, Del Mar C, Wilke K, Winkler E, Barnett A, 2009. Telephone counseling for physical activity and diet in primary care patients. *Am J Prev Med* 36: 142-149.

- Eakin EG, Reeves MM, Marshall AL, Dunstan DW, Graves N, Healy GN, Bleier J, Barnett AG, O'Moore-Sullivan T, et al., 2010. Living Well with Diabetes: A randomized controlled trial of a telephone-delivered intervention for maintenance of weight loss, physical activity and glycaemic control in adults with type 2 diabetes. *BMC Public Health* 10: 452.
- Eyre H, Kahn R, Robertson RM, Clark NG, Doyle C, Hong Y, Gansler T, Glynn T, Smith RA, et al., 2004. Preventing cancer, cardiovascular disease, and diabetes: A common agenda for the American Cancer Society, the American Diabetes Association, and the American Heart Association. *Circulation* 109: 3244-3255.
- Fjeldsoe B, Neuhaus M, Winkler E, Eakin E, 2011. Systematic review of maintenance of behavior change following physical activity and dietary interventions. *Health Psychol* 30: 99-109.
- Fjeldsoe B, Winkler E, Marshall A, Eakin E, Reeves M, 2013. Active adults recall their physical activity differently to less active adults: Test-retest reliability and validity of a physical activity survey. *Health Promot J Austr* 24: 26-31.
- Glasgow RE, Emmons KM, 2007. How can we increase translation of research into practice? Types of evidence needed. *Annu Rev Public Health* 28: 413-433.
- Glasgow RE, Strycker MA, Toobert DJ, Eakin EG, 2000. A social-ecological approach to assessing support for disease self-management: The Chronic Illness Resource Survey. *J Behav Med* 23: 559-583.
- Goldstein MG, Whitlock EP, DePue J, 2004. Multiple behavioral risk factor interventions in primary care: Summary of research evidence. *Am J Prev Med* 27: 61-79.
- Goode AD, Reeves MM, Eakin EG, 2012. Telephone-delivered interventions for physical activity and dietary behavior change: An updated systematic review. *Am J Prev Med* 42: 81-88.
- Graves N, Barnett AG, Halton KA, Veerman JL, Winkler E, Owen N, Reeves MM, Marshall A, Eakin E, 2009. Cost-effectiveness of a telephone-delivered intervention for physical activity and diet. *PLoS ONE* 4: e7135.
- Green LW, Richard L, Potvin L, 1996. Ecological foundations of health promotion. *Am J Health Promot* 10: 270-281.
- Haines PS, Siega-Riz AM, Popkin BM, 1999. The Diet Quality Index revised: A measurement instrument for populations. *J Am Diet Assoc* 99: 697-704.

- Hillsdon M, Cavill N, Nanchahal K, Diamond A, White I, 2001. National level of physical activity: Results from England's ACTIVE for LIFE campaign. *J Epidemiol Community Health* 55: 755-761.
- Hodge A, Patterson A, Brown W, Ireland P, Giles G, 2000. The Anti Cancer Council of Victoria FFQ: Relative validity of nutrient intakes compared with weighed food records in young to middle-aged women in a study of iron supplementation. *Aust N Z J Public Health* 24: 576-583.
- Ireland P, Jolley D, Giles D, O'Dea K, Powles J, Rautishauser I, Wahlqvist ML, Williams J, 1994. Development of the Melbourne FFQ: A food frequency questionnaire for use in an Australian prospective study involving an ethnically diverse cohort. *Asia Pac J Clin Nutr* 3: 19-31.
- Leon AC, Heo M, 2009. Sample sizes required to detect interactions between two binary fixed-effects in a mixed-effects linear regression model. *Comput Stat Data Anal* 53: 603-608.
- Macera C, S.A. H, Yore MM, Jones DA, Ainsworth B, Kimsey D, Kohl HW, 2005. Prevalence of physical activity in the United States: Behavioral Risk Factor Surveillance System 2001. *Prev Chronic Dis* 2: 1-10.
- National Institutes of Health, National Heart Lung and Blood Institute, North American Association for the Study of Obesity, 2000. The practical guide: Identification, evaluation and treatment of overweight and obesity in adults, Bethesda, National Institutes of Health.
- Newby PK, Hu FB, Rimm EB, Smith-Warner SA, Feskanich D, Sampson L, Willett WC, 2003. Reproducibility and validity of the Diet Quality Index Revised as assessed by use of a food-frequency questionnaire. *Am J Clin Nutr* 78: 941-949.
- Pignone MP, Ammerman A, Fernandez L, Orleans CT, Pender N, Woolf S, Lohr KN, Sutton S, 2003. Counseling to promote a healthy diet in adults: A summary of the evidence for the U.S. Preventive Services Task Force. *Am J Prev Med* 24: 75-92.
- Pronk NP, Anderson LH, Crain AL, Martinson BC, O'Connor PJ, Sherwood NE, Whitebird RR, 2004. Meeting recommendations for multiple healthy lifestyle factors. Prevalence, clustering, and predictors among adolescent, adult, and senior health plan members. *Am J Prev Med* 27: 25-33.
- Rutishauser IHE, Webb K, Abraham B, Allsopp R, 2001. Evaluation of short dietary questions from the 1995 National Nutrition Survey, Canberra, Australian Government Department of Health and Ageing.

- Sigal RJ, Kenny GP, Wasserman DH, Castaneda-Sceppa C, White RD, 2006. Physical activity/exercise and type 2 diabetes: A consensus statement from the American Diabetes Association. *Diabetes Care* 29: 1433-1438.
- Sorensen G, Emmons KM, Hunt MK, Barbeau E, Goldman R, Peterson K, Kuntz K, Stoddard A, Berkman L, 2003. Model for incorporating social context in health behavior interventions: Applications for cancer prevention for working-class, multiethnic populations. *Prev Med* 37: 188-197.
- Spark LC, Reeves MM, Fjeldsoe BS, Eakin EG, 2013. Physical activity and/or dietary interventions in breast cancer survivors: A systematic review of the maintenance of outcomes. *J Cancer Surviv* 7: 74-82.
- Stokols D, 1992. Establishing and maintaining healthy environments: Toward a social ecology of health promotion. *Am Psychol* 47: 6-22.
- Timperio A, Salmon J, Crawford D, 2003. Validity and reliability of a physical activity recall instrument among overweight and non-overweight men and women. *J Sci Med Sport* 6: 477-491.
- van Stralen M, De Vries H, Mudde A, Bolman C, Lechner L, 2009. Determinants of initiation and maintenance of physical activity among older adults: A literature review. *Health Psychol* 3: 147-207.
- Vanwormer JJ, Boucher JL, Pronk NP, 2006. Telephone-based counseling improves dietary fat, fruit, and vegetable consumption: A best-evidence synthesis. *J Am Diet Assoc* 106: 1434-1444.
- Waters L, Reeves M, Fjeldsoe B, Eakin E, 2012. Control group improvements in physical activity intervention trials and possible explanatory factors: A systematic review. *J Phys Act Health* 9: 884-895.
- West BT, Welch KB, Galecki AT, 2007. *Linear Mixed Models: A practical guide using statistical software*, Boca Raton, FL, Chapman Hall / CRC Press.
- Williams DM, Lewis BA, Dunsiger S, Whiteley JA, Papandonatos GD, Napolitano MA, Bock BC, Ciccolo JT, Marcus BH, 2008. Comparing psychosocial predictors of physical activity adoption and maintenance. *Ann Behav Med* 36: 186-194.
- Winkler E, Waters L, Eakin E, Fjeldsoe B, Owen N, Reeves M, 2013. Is measurement error altered by participation in a physical activity intervention? *Med Sci Sports Exerc* 45: 1004-1011.

Table 1. Comparison of baseline characteristics of participants with end of intervention and maintenance follow-up data versus those lost to follow-up. Australia, 2005 to 2007.

Characteristic	Telephone Counseling (n = 228)	Usual Care (n = 206)	Follow-up participants (n=306)	Lost to follow-up (n=128)	p ^a
Type 2 diabetes, n (%)	112 (49.1)	85 (41.3)	135 (44.1)	62 (48.4)	0.459
Hypertension, n (%)	199 (87.3)	172 (83.5)	262 (85.6)	109 (85.2)	0.882
Diagnosed with \geq 3 chronic conditions ^b , n (%)	145 (63.6)	114 (55.3)	52 (17.0)	18 (14.1)	0.478
Age, years, <i>mean (SD)</i>	58.7 (11.7)	57.8 (11.9)	57.8 (11.8)	59.3 (11.9)	0.237
Gender, n (% female)	142 (62.3)	123 (59.7)	192 (62.7)	73 (57.0)	0.281
Ethnicity, n (% Caucasian)	206 (90.4)	189 (91.7)	282 (92.2)	113 (88.3)	0.202
Marital status, n (% Married/living together)	160 (70.2)	149 (72.3)	220 (71.9)	89 (69.5)	0.643
Income, n (% \geq \$1000/week) ^c	82 (41.0)	78 (45.3)	113 (42.2)	47 (45.2)	0.641
Education, n (% \geq high school graduate)	105 (46.1)	90 (43.7)	142 (46.4)	53 (41.4)	0.397
Employment, n (% employed)	105 (46.1)	90 (43.7)	144 (47.1)	60 (46.9)	>0.999
Body mass index, kg/m ² , <i>mean (SD)</i>	31.5 (7.1)	30.6 (6.5)	31.2 (6.9)	30.8 (6.6)	0.615
Current smoker, n (%)	28 (12.3)	32 (15.5)	38 (12.4)	22 (17.2)	0.222
CIRS – physical activity, n (% > median) ^d	92 (40.4)	92 (44.7)	133 (43.5)	51 (39.8)	0.524
CIRS – diet, n (% > median) ^e	78 (34.2)	78 (37.9)	118 (38.6)	38 (29.7)	0.081
Moderate to vigorous physical activity, minutes/week, <i>mean (SD)</i>	142.5 (226.2)	142.4 (197.3)	142.5 (207.8)	142.3(224.7)	0.992
% Energy from total fat, <i>mean (SD)</i>	36.8 (5.0)	36.9 (5.5)	36.7 (5.3)	37.3 (5.0)	0.273
% Energy from saturated fat, <i>mean (SD)</i>	14.5 (3.3)	14.2 (3.4)	14.3 (3.2)	14.5 (3.6)	0.508
Servings of vegetables, <i>mean (SD)</i>	3.0 (1.7)	3.0 (1.7)	3.0 (1.7)	2.8 (1.6)	0.133
Fiber intake, grams, <i>mean (SD)</i>	22.4 (7.8)	21.6 (8.1)	21.7 (7.8)	22.7 (8.0)	0.202
Servings of fruit, <i>mean (SD)</i>	1.6 (1.0)	1.5 (1.3)	1.6 (1.2)	1.4 (1.0)	0.106

^a p for difference by completion status (t-test or chi-square)

^b Number of chronic conditions participants reported from the following list: diabetes, hypertension, cardiovascular disease, stroke, arthritis, lung condition, osteoporosis, cancer, depression and anxiety.

^c Percentages exclude those with missing income (28 Telephone Counseling, 34 Usual Care, 38 Followed up and 24 Lost to Follow-up)

^d Median Chronic Illness Resources Score (CIRS) for physical activity =2.0 ^e Median Chronic Illness Resources Score (CIRS) for diet =2.4

Table 2. Moderation of intervention effects on physical activity outcomes at 12 month end of intervention (12M) and 18 month maintenance (18M) in Telephone Counseling (n=142) and Usual Care participants (n=164)^a. Australia, 2005 to 2007.

		n TC/UC	Physical activity (PA) duration (minutes/week)	
			12M	18M
<i>Social support (Physical Activity) Score</i> ^b	Low, < median (2)	79/94	30.28 (36.25)	5.27 (36.25)
	High, ≥ median (2)	63/70	-87.17 (41.30)*	-73.45 (41.30)
Moderation (Group x Social Support)			p=0.033	p=0.152
Group x Social Support x Time				p=0.563
<i>Baseline Physical Activity</i>	Low, < median (60 min/week)	70/92	57.21 (38.68)	-32.19 (38.68)
	High, ≥ median (60 min/week)	72/72	-109.56 (40.65)*	-28.34 (40.65)
Group x Physical Activity			p=0.003	p=0.945
Group x Physical Activity x Time				p=0.010

Table presents Group difference (Telephone Counseling – Usual Care)(Standard error) within each level of the moderating variables, and p-values for group by moderator interaction at 12M and 18M, and group by moderator by time interactions (18 vs 12M).

^a Analyses are limited to participants with data at baseline, 12-months and 18-months

^b Social support for physical activity as measured by Chronic Illness Resources Survey

*significant intervention effect p<0.05

Table 3. Moderation of intervention effects on fruit and vegetable intake at 12 month end of intervention (12M) and 18 month maintenance (18M) in Telephone Counseling (n=142) and Usual Care (n=164) participants ^a. Australia, 2005 to 2007.

		n	Fruit Intake (servings/day)		Vegetable Intake (servings/day)	
		TC/UC	12M	18M	12M	18M
<i>Gender</i>	Males	58/56	0.70 (0.17)*	0.54 (0.17)*	1.22 (0.31)*	0.98 (0.31)*
	Females	84/108	0.22 (0.13)	0.09 (0.13)	0.69 (0.24)*	0.57 (0.24)*
Group x Gender			p = 0.026	p = 0.037	p=0.167	p=0.287
Group x Gender x Time				p = 0.894		p=0.778
<i>Marital Status</i>	Not married	36/50	0.61 (0.20)*	0.80 (0.20)*	0.50 (0.36)	0.46 (0.36)
	Married	106/114	0.33 (0.12)*	0.08 (0.12)	1.04 (0.22)*	0.84 (0.22)*
Group x Marital Status			p = 0.235	p = 0.002	p=0.192	p=0.363
Group x Marital Status x Time				p=0.071		p=0.728

Table presents Group difference (Telephone Counselling – Usual Care) (Standard error) within each level of the moderating variables, and p-values for group by moderator interaction at 12M and 18M, and group by moderator by time interactions (18 vs 12M).

^a Analyses are limited to participants with data at baseline, 12-months and 18-months

*significant intervention effect p<0.05

Table 4. Moderation of intervention effects on saturated fat, total fat and fiber intake at 12 month end of intervention (12M) and 18 month maintenance (18M) in Telephone Counseling (n=139) and Usual Care (n=161) participants^a. Australia, 2005 to 2007.

		n TC/UC	Saturated Fat		Total Fat		Fiber	
			12M	18M	12M	18M	12M	18M
<i>Marital Status</i>	Not married	34/49	-1.74(0.57)*	-1.73 (0.57)*	-2.75 (0.92)*	-4.75(0.92)*	3.71 (1.39)*	2.71 (1.39)
	Married	105/112	-1.45(0.35)*	-1.20 (0.35)*	-1.23 (0.56)*	-0.61(0.56)	2.51 (0.85)*	2.70 (0.85)*
Group x Marital status			p=0.667	p=0.437	p=0.161	p<0.001	p=0.462	p=0.994
Group x Marital status x Time				p=0.710		p=0.020		p=0.525
<i>BMI</i> ^b	Healthy/underweight	26/26	-2.18(0.72)*	-1.73 (0.72)	-1.76 (1.15)	0.07 (1.15)	3.59 (1.71)*	2.69 (1.71)
	Overweight	55/51	-1.28(0.50)*	-1.04 (0.50)*	-1.07 (0.81)	-1.17 (0.81)	4.06 (1.20)*	5.76 (1.20)*
	Obese	58/84	-1.47(0.44)*	-1.48 (0.44)*	-1.99 (0.71)	-2.74(0.71)*	1.54 (1.05)	0.75 (1.05)
Group x BMI			p=0.5794	p=0.6869	p=0.6839	p=0.0859	p=0.2507	p=0.007
Group x BMI x Time				p=0.8296		p=0.1931		p=0.3404
<i>Chronic Conditions</i> ^c	<3	62/58	-2.05(0.47)*	-1.62 (0.47)*	-2.86 (0.76)*	-2.67(0.76)*	2.73 (1.14)*	2.57 (1.14)*
	3+	77/103	-1.16(0.39)*	-1.17 (0.39)*	-0.73 (0.63)	-1.31(0.63)*	2.85 (0.94)*	2.75 (0.94)*
Group x Conditions			p=0.142	p=0.418	p=0.031	p=0.287	p=0.937	p=0.903
Group x Conditions x Time				p=0.427		p=0.297		p=0.970
<i>Social Support – Diet</i> ^d	Low, <2.4	82/101	-1.86(0.38)*	-1.85 (0.38)*	-2.28 (0.62)*	-2.68(0.62)*	2.81 (0.93)*	2.41 (0.93)
	High, ≥2.4	57/60	-1.05(0.48)*	-0.60 (0.48)	-0.72 (0.77)	-0.37 (0.77)	2.98 (1.15)*	3.04 (1.15)*
Group x Social Support			p=0.185	p=0.043	p=0.115	p=0.020	p=0.911	p=0.673
Group x Social Support x Time				p=0.452		p=0.471		p=0.786
<i>Baseline diet</i>	Low, < median ^e	77/73	-1.22 (0.44)*	-1.48 (0.44)*	-1.12 (0.72)	-2.02 (0.72)*	2.05 (1.13)	1.10 (1.13)
	High, ≥ median	62/88	-1.74 (0.44)*	-1.11 (0.44)*	-2.06 (0.73)*	-1.34 (0.73)	3.54 (1.16)*	4.17 (1.16)*
Group x Fiber			p=0.412	p=0.553	p=0.361	p=0.506	p=0.357	p=0.058
Group x Fiber x Time				p=0.115		p=0.108		p=0.343

Table presents Group difference (Telephone Counseling – Usual Care) (Standard Error) within each level of the moderating variables, and p-values for group by moderator interaction at 12M and 18M, and group by time by moderator interactions (18 vs 12M).

^a Analyses are limited to participants with valid Food Frequency data at baseline, 12-months and 18-months

^b Body Mass Index (BMI), kg/m²

^c Number of chronic conditions participants reported from the following list: diabetes, hypertension, cardiovascular disease, stroke, arthritis, lung condition, osteoporosis, cancer, depression and anxiety.

^d Social support for diet as measured by Chronic Illness Resources Survey (CIRS); median value = 2.4

^e Median = 13.9 %E saturated fat, 36.6 %E fat, 20.7 g/day fiber

*significant intervention effect $p < 0.05$

Figure 1: Changes from baseline in physical activity within intervention (n=142) and usual care (n=164) groups by moderator status. Australia, 2005 to 2007.

Figure 2: Changes from baseline in fruit intake within intervention (n=142) and usual care (n=164) groups by moderator status. Australia, 2005 to 2007.

Figure 3: Changes from baseline in dietary intake within intervention (n=139) and usual care groups (n=161) by moderator status. Australia, 2005 to 2007.