Physical activity and fitness outcomes of a lifestyle intervention for primary care patients with depression and anxiety : A randomised controlled trial

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Abstract

Patients currently being treated for depression and/or anxiety were referred by their GP and randomised to a 12-week individually tailored diet and exercise lifestyle intervention or an attention control group. Assessments at baseline and 12 weeks included the Active Australia Survey for self-reported physical activity, chair stands, arm curls and a 3-minute step test to measure physical fitness.

Intent-to-treat analyses using linear mixed modelling showed both groups significantly improved participation in physical activity and muscular endurance. There were no significant differences in improvement between groups. The only group by time interaction was found for body mass index and indicated greater improvement in the intervention group compared to the attention control group. Motivated patients with depression and/or anxiety may be able to increase their participation in physical activity without regular individual support from an exercise physiologist. Alternate modes of support should be considered.

Key words

Depressive disorder, anxiety, physical activity, physical fitness

Introduction

Almost half of all Australians will experience a mental disorder in their lifetime, and twenty percent of Australian adults experience a mental disorder each year (Australian Bureau of Statistics, 2009). Depression, anxiety and substance abuse are the leading diagnoses of mental illness in Australia (Australian Institute of Health and Welfare, 2012), and are most commonly treated with medication and psychological interventions (Royal Australian and New Zealand College of Psychiatrists Clinical Practice Guidelines Team for Depression, 2004). Exercise and Sports Science Australia has recommended that exercise should be considered as a treatment for depression, and that it may also be moderately effective as a treatment for anxiety (Morgan et al., 2013). Despite growing interest and evidence to support exercise interventions in the treatment of mental disorders including depression and anxiety, little is known about the optimal method of delivery of these services.

The aim of this randomised controlled trial was to determine whether an individually tailored lifestyle intervention delivered in a primary care setting could improve the mental health outcomes of patients being treated for depression and/or anxiety compared to an attention control. This paper will report the secondary outcomes of fitness and participation in physical activity.

The authors declare no known conflicts of interest.

Methods

Between 2006 and 2008, general practitioners (GPs) of a large primary care organisation (Illawarra Division of General Practice) were invited to refer adult patients currently being treated for depression and anxiety. Patients under 18 years of age and those with contraindications to participation in physical activity were excluded from the study. Eligible participants were individually randomised by GP in order of referral using a randomisation chart

generated by www.randomization.com. The treating dietitan/exercise physiologists (DEPs) were aware of the randomisation sequence. Participants were assigned to either an intervention or an attention control condition. Participants were informed of their group allocation at the end of the baseline assessment.

The intervention was modelled on the Chronic Disease Management Scheme (Newland & Zwar, 2006) where eligible patients can receive up to five rebated visits to allied health professionals annually. Once referred, patients were eligible for five visits to the DEP, under the Chronic Disease Management Plan plus they received one extra assessment for research purposes. These visits included an initial assessment, four consultations and a final assessment. Visits were initially scheduled approximately fortnightly over a 12 week period. Patients were seen at clinics in GP surgeries or in consulting rooms at the Psychology Clinic at the local University campus. A discussion of considerations involved in the development of this study, and changes made based on an initial pilot study are reviewed elsewhere (Forsyth et al., 2009).

Three dual qualified DEPs conducted the intervention including consultations and telephone contact with attention control participants. All DEPs had completed a Master of Science in Nutrition, Dietetics and Exercise Rehabilitation and received additional training in motivational interviewing. Assessments were performed by DEPs or trained final year Nutrition and Exercise Science students. All 12-week assessments were completed by a student or DEP who was not the treating practitioner.

The first visit involved obtaining informed consent, taking baseline measures and collecting completed self-report questionnaires. Intervention participants returned for four individual consultations, and attention control participants were contacted by telephone at similar intervals. All participants returned for a final assessment at 12-weeks. GPs were sent reports of patient results and progress after each assessment and consultation.

The initial consultation was structured to elicit participants' beliefs, motivations and goals for their health and lifestyle. Motivational interviewing was used in consultations to enhance patient engagement and adherence (Rollnick, 1996). A goal-based approach was used to develop individually tailored patients programs designed according to patient readiness to change for diet and exercise behaviours (Prochaska & DiClemente, 1982). All dietary and physical activity changes were client-driven, and designed to be sustainable, affordable, progressive, suitable to the participant's lifestyle, and able to be performed without professional supervision. All nutrition and physical activity advice was primarily based on the Australian Guide to Healthy Eating (Department of Health and Ageing, 1998) and the Physical Activity Guidelines for Australian Adults (Department of Health and Ageing, 2004). This study did not provide a specific nutrition or physical activity intervention, rather it followed the individualised approach of a large diabetes prevention program that stated: *'Our lifestyle intervention was systematic and intensive, with the study participants receiving detailed, individualized counseling. The study, however, was not designed to test the relative contributions of dietary changes, increased physical activity, and weight loss to the reduction in the risk of diabetes, and the effects of these components remain to be determined'* (Diabetes Prevention Program Research Group, 2002, p. 398).

With facilitation from the DEPs, participants developed short-term goals, identified relevant homework activities, and addressed perceived barriers to participation in homework activities. Homework was recorded on a standard form (Kazantzis et al., 2000) at the end of each session and reviewed at the start of the subsequent session. Most participants worked towards multiple goals throughout the program, including dietary, exercise and other lifestyle related goals. The most commonly chosen physical activity goals include walking, home resistance exercises, gym attendance, cycling and swimming. Smaller numbers of participants choose to

increase incidental activity, run, participate in home aerobic exercises or play organised sport. All intervention participants continued with usual care provided by their GPs for the duration of the intervention. Participants assigned to the attention control condition received phone calls from the DEPs at similar intervals to the intervention consultations. Each telephone call typically lasted for five minutes. DEPs asked participants whether they had made any changes to their diet or physical activity patterns, but did not provide advice. Participants in the attention control condition continued with usual care for the duration of the intervention, and were offered the intervention at the end of the 12-week period.

Baseline age, sex, self-reported mental health conditions and GP-reported mental health conditions were recorded. Anthropometric measurements including height, weight, waist circumference and blood pressure were measured. Body mass index (BMI) was calculated by dividing weight in kilograms by height in metres squared. A BMI of 18.5 – 24.9 kg m^2 was considered to be within a healthy weight range. The Depression Anxiety and Stress Scale (DASS-21) was used to measure mental health. The DASS-21 has 21 items comprising three subscales measuring the negative emotional states of depression, anxiety and stress (Lovibond & Lovibond, 1995).

The Active Australia Survey (Australian Sports Commission, 1998) was used to measure self-reported participation in physical activity. The Active Australia Survey is composed of two sections. The first asks participants to record the number of occasions and total number of minutes over the past week that they have spent in each of (1) continuous walking, (2) vigorous physical activity and (3) moderate physical activity. The second section asks participants to estimate the total time spent in sedentary recreation on (1) weekdays and (2) weekend days over the past week. This has been found to be a valid (71.8% agreement with other surveys) and

reliable (intra-class correlation 0.64) instrument to measure self-reported physical activity (Brown et al., 2004).

The chair stand test and arm curl test from the Senior's Fitness Battery (Rickli & Jones, 1999a) were selected to measure upper and lower limb muscular endurance. These tests measure the number of arm curls or repeated standing from a chair participants can achieve over 30 seconds. The validity of these have not been widely demonstrated in young adults, but in the present study these tools were sensitive enough to detect significant changes over time including amongst fit, young individuals. The results were compared to gender and age specific norms (Rickli & Jones, 1999b) to generate muscular endurance ratings of well below average, below average, average, above average or well above average. The results of participants under 60 years were compared with the youngest available norms. The chair stand test is both reliable (intraclass correlation R = 0.89) and valid (r = 0.77, compared to 1 RM leg press gold standard) (Rickli & Jones, 1999a). The arm curl test is also reliable (intraclass correlation R = 0.81) and valid (r = 0.78, compared to combined 1 RM chest press, biceps and upper back gold standard) (Rickli & Jones, 1999a).

The YMCA step test (Golding, 2000) was chosen as a measure of aerobic fitness because it is a portable measure with good validity and reliability. This test involves stepping 30 cm at a cadence of 96 beats per minute (or equivalent to 24 complete steps each minute) for three minutes. Post-test heart rate is taken between 5 and 20 seconds following completion of the test, and compared to gender and age specific norms to generate an aerobic fitness rating of very poor, poor, below average, average, above average, good or excellent. The YMCA step test (also known as the Kasch step test) has been demonstrated to have acceptable reliability and validity compared to treadmill testing (r = 0.95, Kasch et al., 1966).

The data from all participants who commenced the study were included in an intention to treat analysis. Due to high levels of attrition there was a large amount of missing data with 35% loss to follow up, therefore the effectiveness of the lifestyle intervention was assessed using SPSS with linear mixed model analyses (also known as multilevel modelling or hierarchical linear modelling). A linear mixed model analysis was performed by assessing interaction and main effects of group and time for all dependent variables. Before analysis, data for all variables were inspected for missing values, normality and outliers. Violations of normality were identified for BMI (moderate positive skew) and measures of physical activity (severe positive skew). These were addressed by transforming BMI into the square root of the original measure, and by applying a log followed by an inverse transformation to measures of physical activity.

Potential moderating factors were; gender (Chen et al., 2006), other treatment modalities (Hale, 1997), reason for referral, years since diagnosis and recurrence of condition within 12 months. These factors were examined by incorporating them into the linear mixed model as fixed effects and testing each variable separately. Tests of significance less than or equal to 0.05 were considered statistically significant. To examine the moderating effects, post hoc between groups t-tests at baseline and post-test were conducted for all moderating factors found to have a significant effect on the linear mixed model. Figures were created to demonstrate changes in primary outcome variables and variables where there were significant differences for group, time or group x time effects.

This study was part of the Australian Integrated Mental Health Initiative, which was a five-year National Health and Medical Research Council funded program aimed at improving recovery from mental illness. Additional funding was received from the Illawarra Division of General Practice. The funding bodies were not involved in data collection, analysis, interpretation

or the decision to submit results for publication. This study was reviewed and approved by the University of Wollongong Human Research Ethics Committee and all participants completed written informed consent prior to participation in this study. All authors certify responsibility for this manuscript.

Results

Over a two year period, 34 GPs referred 119 patients ranging in age from 18 to 84 years to the study. Figure 1 provides the participant flow diagram through the study. Two patients under the age of 18 were referred and excluded from the study. All other referred patients were randomized. Nine of 61 patients allocated to the intervention declined the referral, as did 14 of 56 patients allocated to the attention control. Overall, 94 met the inclusion criteria and completed an initial assessment. At the time of the initial assessment, there were 14 males and 38 females in the intervention group, and 12 males and 30 females in the attention control group.

For assessment purposes, patients were considered to have dropped out if they did not attend the final assessment. There were 21 drop outs and 31 completers in the intervention group, and 13 drop outs and 29 completers in the attention control. Reasons for drop out were not generally provided, though some participants cited lack of time. All 'completed' patients attended both the initial and final assessments and at least two of four consultations. Baseline total DASS and DASS anxiety scores were not significantly different between participants who did not complete the study protocol (Mean = 26.2, SD = 14.9 for total DASS; Mean = 6.7, SD = 4.9 for anxiety) compared to those who did complete the study program (Mean = 21.1, SD = 11.7 for total DASS; Mean = 4.7, SD = 3.7 for anxiety) [$t(92) = -1.8$, $p = .80$ for total DASS; $t(92) = 2.2$, $p = .70$ for anxiety]. Non-completers did not differ from other study participants on any of the other measures tested.

Data was available from 94 participants who were included in the analyses. At baseline, there were no significant differences between the intervention and attention control groups on a range of descriptive and outcome variables despite trends toward lower DASS scores, higher Australian Healthy Eating Index scores (Throw, 2007), and greater numbers referred with anxiety in the intervention group. A t-test found a significant between group difference only for total DASS scores at baseline ($p < 0.05$) (see Table 1). For a detailed description and discussion of the baseline characteristics of this patient population see Forsyth et al. (2015b).

Changes in measures of depression, anxiety, nutrient intake and diet quality are presented elsewhere (Forsyth et al., 2015a).

There were significant improvements from pre-to-post-test across measures of physical activity ($p < 0.05$) and muscular endurance ($p < 0.001$), and near significant improvements over time in aerobic fitness ($p = 0.05$), diastolic blood pressure ($p = 0.05$), weight ($p = 0.05$) and BMI ($p = 0.08$) in both groups. There was a significant Group x Time interaction effect for BMI ($p < 0.05$) with greater improvement in the intervention group than the attention control group (see Table 2).

Moderating factors did not impact on the outcome of physical activity and fitness levels except for reason for referral which had a significant effect on change in physical activity level ($p < 0.05$). Patients referred with depression (Mean = 242.4 weekly minutes, SD = 239.1), $t (71.3) = 2.3$, $p <0 .05$, spent significantly less time in physical activity than those referred with anxiety (Mean = 410.2 weekly minutes, SD = 462.6) or both depression and anxiety (Mean = 407.9 weekly minutes, SD = 426.1).

Discussion

Both the intervention and attention control groups improved their participation in physical activity and their fitness levels over the course of the study period. Improvements in the intervention group were expected and are consistent with findings of studies in which clinical exercise prescription has led to improvements in symptoms of depression (Rimer et al., 2012).

Control group improvements in physical activity trials occur in more than 25% of trials and may be attributed to behavioural measurements (monitoring) and participant characteristics (Waters et al., 2012). Several factors may have contributed to the positive outcome for control group participants in this study. All participants in this study were aware of their depression and/or anxiety and voluntarily seeking treatment from their GP. They had agreed to take part in the lifestyle intervention, either immediately or following a 12-week delay, demonstrating a readiness to change and desire to modify lifestyle behaviours. Improvements may have also been a result of other concurrent treatment such as medication or counselling which could have directly improved mental health, and indirectly improved lifestyle behaviours through increased motivation.

Aspects of the attention control condition may also have prompted and encouraged participants to increase their participation in physical activity. Attention control group participants took part in an initial assessment and received phone calls at the same intervals as intervention group face-to-face appointments. While no advice or motivational interviewing techniques were employed during the phone calls, patients were aware that the DEP would be calling at regular intervals and asking about any changes to their physical activity patterns. It is possible that these prompts motivated participants to be more accountable for their lifestyle behaviours. The extensive assessment process would have also drawn attention to health and lifestyle goals. For some participants this may have developed discrepancy between current behaviours and desired outcomes and motivated them to adopt or increase participation in

physical activity. For others, participation in the physical assessment could have improved their self-efficacy beliefs which are known to predict health outcomes (Bandura, 2005).

Lower levels of participation in physical activity at baseline for patients referred with depression may be related to difficulty with motivation to participate in physical activities. Prior reviews have found that baseline depression is significantly associated with subsequent sedentary lifestyle and poor adherence to exercise prescriptions (Roshanaei-Moghaddam et al., 2009). However, at least one study that examined the transition between activity and inactive recreational activity patterns has found that major depression increased the risk of transition into inactive patterns for those previously active, but did not affect the probability of moving from an inactive to an active lifestyle (Patten et al., 2009). This is promising as it suggests that while depression may be associated with lower levels of physical activity, it does not necessarily predict a poor response to behaviour modification. In our study, desired behaviours were planned, and this activity scheduling may have assisted participants to adhere to their physical activity goals.

There are a number of limitations that may affect the generalisability of these results. Adherence to self-selected goals was not systematically assessed. Treatment compliance can predict outcomes (Mattson et al., 1998). In this case, outcome measures such as changes in physical activity or fitness levels may indicate compliance, thus those participants who improved on these variables are most likely to have complied with their homework. Because both the attention control and the intervention groups improved on these variables over time, it is possible that members of the attention control group were also participating in increased levels of physical activity. This spontaneous activity may have occurred as a result of referral to the program, extensive assessment of diet and exercise factors and participant expectations that some intervention had been initiated and would lead to change.

Physical activity levels of participants in this study were greater than those of the general population at baseline, as described in Forsyth et al. (2015a). As such, there was less 'room for improvement' in this study population, and even small changes, which may be too small to demonstrate significance in a sample of this size, would indicate a considerable improvement and greater alignment with the National Physical Activity Guidelines.

Reason for referral was identified to be a moderating factor for changes in physical activity, and the intervention group had more than twice as many participants referred with anxiety (n=13) as the attention control group (n=6). It is possible that participants with higher levels of anxiety may have experienced greater perceived barriers to behaviour change.

There was a high, but not unexpected, rate of attrition in this study, with only 64% of participants completing the study protocol. This is similar to the rate of completion in other trials involving participants with mental illness (Dimidijian et al., 2006; White et al., 2010). Although this was a limitation of the study, missing data was able to be inferred through the use of the linear mixed model and multivariate analyses.

Conclusion

A formal lifestyle intervention for patients with depression and anxiety, such as that described in this study, can be successful in improving their physical fitness and participation in physical activity. However, such an approach is not essential to effect lifestyle behaviour change in primary care patients being treated for depression and/or anxiety. The attention control group participants in this study improved their fitness and physical activity to a similar extent as program participants. This may reflect factors such as a readiness to change, receiving concurrent pharmacotherapy or psychotherapy, being held accountable with regular phone calls, or participating in an extensive assessment of fitness and physical activity. Based on these findings,

it is likely that other program modalities such as telephonic and online services could provide similar benefit to more intensive face-to-face individualised programs.

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Adrienne Forsyth, Frank Deane and Peter Williams declare that they have no conflict of interest. All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000 (5). Informed consent was obtained from all patients for being included in the study.

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Table 1 Demographic, treatment, and clinical characteristics of both groups at baseline

	Intervention (n=52)			**Attention Control** (n=42)		
	Mean	SD	n%	Mean	SD	n%
BMI (kg/m^2)	31.6	7.5		31.8	6.6	
Total DASS score	21.2 [a]	13.2		26.5 [a]	13.7	
Total weekly minutes in physical activity	331.6	384.6		318.4	330.9	
Total Aust-HEI score	43.6	9.2		42.9	9.1	
Number referred with depression			24 (46%)			23 (55%)
Number referred with anxiety			13 (25%)			6 (14%)
Number referred with both depression and anxiety			15 (29%)			13 (31%)
Number being treated by a psychiatrist			10 (19%)			7 (17%)
Number reporting a recurrence this year			41 (79%)			37 (88%)

Note: [a] significant between group difference at $p < .05$. Aust-HEI = Australian Healthy Eating Index.

Table 2 Changes in fitness, physical activity and anthropometric measures over time.

		Attention Control			**Intervention**			**p-value**	**p-value**	**p-value**
		Pre test	Post test	Difference (% change)	Pre test	Post test	Difference (% change)	**Group effect**	**Time effect**	**Group x Time effect**
Total time in physical activity (minutes per week) *	Mean (SD) [n]	318.4 (330.9) [42]	432.4 (471.7) [31]	114.0 (35.8%)	331.6 (384.6) [52]	434.5 (355.8) [31]	102.9 (31.0%)	.87	.04 [a]	.73
	Median (interquartile range)	185.0 (60.0, 495.0)	285.0 (77.9, 565.0)	100.0 (54.0%)	197.5 (22.5, 537.5)	300.0 (150.0, 675.0)	102.5 (51.9%)			
Time in moderate physical activity (minutes per week) *	Mean (SD) [n]	140.4 (205.0) [37]	153.8 (246.4) [29]	13.4 (9.5%)	102.8 (176.1) [50]	98.7 (160.0) [31]	-4.1 (-4.0%)	.92	.22	.67
	Median (interquartile range)	50.0 (0.0, 180.0)	142.5 (30.0, 624.0)	92.5 (185%)	32.5 (0.0, 120.0)	60.0 (1.0, 120.0)	27.5 (84.6%)			
Time in vigorous physical activity (minutes per week) *	Mean (SD) [n]	36.6 (72.5) [41]	69.7 (100.3) [30]	36.1 (98.6%)	59.0 (99.9) [50]	91.1 (104.9) [31]	32.1 (54.4%)	.80	.50	.85
	Median (interquartile range)	0.0 (0.0, 30.0)	97.5 (0.0, 222.0)	97.5	0.0 (0.0, 97.5)	60.0 (0.0, 150.0)	60.0			
YMCA step test (heart rate/minute)	Mean (SD) [n]	119.5 (15.6) [36]	122.8 (22.0) [27]	3.8 (3.2%)	123.8 (22.5) [42]	116.6 (19.1) [27]	-7.2 (-5.8%)	.99	.05 [a]	.37
Muscular endurance (Chair stands + arm curls	Mean (SD) [n]	30.9 (6.4) [41]	35.2 (7.6) [29]	4.3 (13.9%)	32.3 (8.2) [52]	37.5 (11.6) [31]	5.2 (16.1%)	.31	.00 [b]	.59

		Attention Control			Intervention			p-value	p-value	p-value
in 30 seconds)										
Systolic blood pressure (mmHg)	Mean (SD) [n]	140.0 (19.0) [42]	132.3 (18.7) [30]	-7.7 (-5.5%)	133.4 (14.1) [52]	134.0 (15.0) [31]	0.6 (0.4%)	.32	.23	.09
Diastolic blood pressure (mmHg)	Mean (SD) [n]	84.4 (9.6) [42]	81.2 (9.8) [30]	-3.2 (-3.8%)	83.6 (9.6) [52]	81.6 (8.5) [31]	-2.0 (-2.4%)	.91	.05 [a]	.58
Weight (kg)	Mean (SD) [n]	88.0 (18.9) [42]	86.5 (18.7) [30]	-1.5 (-1.7%)	90.6 (25.6) [32]	88.7 (24.2) [52]	-1.9 (-2.1%)	.91	.04 [a]	.58
BMI (kg/m^2) *	Mean (SD) [n]	31.8 (6.6) [42]	31.1 (7.1) [30]	-0.7 (-2.2%)	31.6 (7.5) [52]	30.7 (8.1) [32]	-0.9 (-2.8%)	.64	.08	.04 [a]
	Median (interquartile range)	30.4 (27.1, 35.7)	30.1 (26.6, 35.7)	-0.3 (-1.0%)	30.9 (27.1, 35.8)	29.6 (23.4, 35.8)	-1.3 (-4.2%)			

Note. [a] significant difference at $p < .05$ [b] significant difference at $p < .001$ * expressed also as median (interquartile range). Pre and post values expressed as mean. Where data was highly skewed, median valued are also reported. Differences between groups, over time, and group by time interactions for dependent variables displayed as p values.

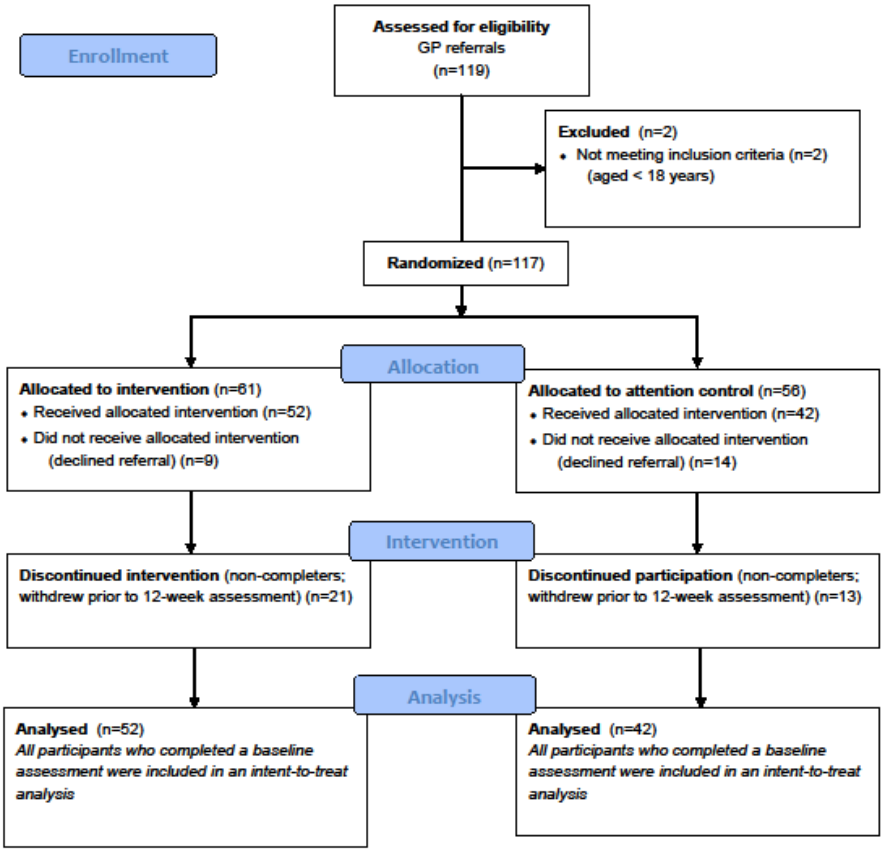

Figure 1. Participant flow diagram