- 1 A randomized controlled trial on the effects of a 6-month home-based physical activity
- 2 program with individual goal-setting and volunteer mentors on physical activity, adherence
- 3 and physical fitness in inactive older adults at risk of cognitive decline: The INDIGO Study
- 4
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1 Abstract

2 Background:

Increasing physical activity (PA) in those who have memory concerns requires innovative
approaches.

5 **Objective:**

To compare in this randomized controlled trial (RCT) the effects on PA, adherence and fitness of
two approaches to deliver a 6-month home-based PA program in older, inactive individuals at risk
of cognitive decline.

9 Methods:

10 Individuals (n = 52) aged 60-85 years, inactive with mild cognitive impairment or subjective

11 cognitive decline were recruited from the community and memory clinics. Randomization was to 6-

12 months of 150 minutes/week moderate intensity PA with either: goal-setting with mentor support;

or education and peer contact. A subset of participants (n = 36) continued for a further 6 months.

14 PA, moderate and vigorous PA and secondary outcomes, fitness, goal performance/satisfaction

and self-efficacy were assessed at baseline, 6 and 12 months. Modelling of primary and

16 secondary outcomes was conducted with linear mixed models.

17 **Results:**

Participants were mean age (\pm sd) 70.1 (6.4) years. Six-month retention was 88.5% (n = 46). No significant between-group differences were observed for PA or fitness. Post-hoc combined group data showed a significant, moderate-large effect size increase in PA with time. PA increased by a mean 1,662 (943, 2383) steps/day (95% CI) and 1,320 (603, 2037) steps/day at 6 and 12 months (p < 0.001).

Median (quartiles Q1-Q3) 6 and 6-12 month combined group adherence was 88.9 (74.4 - 95.7)%
and 84.6 (73.9 - 95.4)% respectively.

25 Conclusion:

- 1 In this target group, no differences were detected between groups both intervention strategies
- 2 were highly effective in increasing PA and fitness.
- 3

4 WORD COUNT:250

1 BACKGROUND

2 Even though the benefits of regular physical activity (PA) are well known and supported by a 3 growing body of evidence that PA is beneficial for cognitive health [1], finding effective strategies to 4 increase the adoption and maintenance of PA for older and inactive individuals is an ongoing 5 significant challenge. Much more complex challenges are present when older people have 6 difficulties with memory loss or declining cognitive function that may limit understanding of 7 instructions and execution of tasks, [2, 3] as well as motivation and capacity to change behaviour, 8 while often experiencing decline in physical function such as poor fitness, strength and balance [4, 9 5].. In our previous work we have been successful in achieving excellent adherence to homebased PA over 6 months [6, 7] and 24 months [8] for older adults with mild cognitive impairment 10 (MCI) or subjective cognitive decline (SCD) at increased risk of Alzheimer's disease (AD). 11 12 However, these studies included participants who were already undertaking regular moderate intensity PA. In the current study, we explore whether a modified PA program can lead to the 13 uptake and the adoption of PA in physically inactive individuals in this target group. 14

15 Goal-setting is an effective strategy to increase PA in older adults [9, 10]. Personalized goalsetting was rated as a highly positive intervention strategy by participants who were successful in 16 improving their PA profile [11]. The efficacy of an individual goal-oriented approach to behavior 17 change has been demonstrated in community living older adults and in those with mild dementia, 18 19 with improved goal performance and satisfaction, increased physical and cognitive activity, feasibility and acceptability by older adults [12, 13, 14]. Further, individual goal-oriented cognitive 20 21 rehabilitation (CR) improved everyday functioning in relation to individual goals targeted in the 22 therapy for people with mild-to-moderate dementia [14]. When mentoring was added to this goal orientation approach there were further benefits in PA, global cognition, memory and body 23 composition compared to goal-setting alone [13]. Mentorship motivated people to work on goals 24 25 and was well received [15].

Peer mentoring in older adults is as effective in achieving retention, participation and increases in
fitness as a similar program delivered by young professionals [16]. When peer mentors are

volunteers this approach has the potential to be a cost-effective delivery model to increase PA
among older adults [16]. Significantly greater long-term increases in moderate and vigorous PA
were achieved with peer-delivered PA compared to community delivered PA programs [17]. In a
systematic review of 10 studies on peer-delivered interventions the authors concluded that
compared to other programs peer delivery was just as effective as professional delivery and more
effective than control programs in increasing PA [18].

7 Combining the strategies of an individual goal-oriented approach developed by Clare and 8 colleagues [12,14], modified to target PA and physical function (PF) goals, with support from 9 physically active peers to promote increased PA in inactive older adults at risk of cognitive decline 10 is a novel approach. To our knowledge, this is the first study to utilize peer mentoring to promote PA in this target group. The primary aim of this randomized controlled trial (RCT) was to determine 11 12 if a 6-month home-based PA intervention with individual goal-setting and peer mentors (intervention group) would result in a significantly greater increase in PA compared to the same PA 13 program delivered with standard education and peer contact only (control group) after 6 (short-14 term) and 12 months (long-term). The long-term effects of this intervention were assessed from a 15 16 sub-group of participants after 12 months. Secondary aims included evaluation of functional 17 fitness, goal performance, goal satisfaction and program factors at 6 and 12 months. Further, to explore the factors that influence the change in the primary and secondary outcomes. 18

19

20 METHODS

21 Study Design

The protocol for this parallel group single-blind RCT based on CONSORT guidelines (Figure 1) has been previously published [19]. The study was registered with the Australia New Zealand Clinical Trials Registry registration number ACTRN12613001181796. The trial had two components; mentoring/peer contact training and implementation, and a PA intervention. The main outcomes of the intervention were the change in PA and adherence to the PA program for participants in the PA intervention. Secondary outcomes included functional fitness components, goal performance, goal

1 satisfaction, self-efficacy and program evaluation. The original protocol was for a 6-month PA 2 intervention with a further 6-months follow-up. Due to recruitment challenges and funding restrictions, the protocol was amended with the trial period limited to 6 months after the first 36 3 4 participants. Another 16 participants were recruited for the 6-month intervention period only (the 6-5 month cohort). Hence a total of 52, participated in the 6-month intervention with a subset (n = 36)following the original protocol with a further 6-month follow-up (the 12-month cohort). These 6 7 participants were asked to continue with their PA program during the 6-12 month period recording sessions in their PA diaries but without any of the support given in the first 6 months such as 8 9 workshops or phone calls. Table 1 outlines the components of the intervention and control group programs and highlights the similarities and differences. The methods relevant to this paper are 10 described briefly below. 11

12 Participants

Participants were independent-living older adults aged 60-85 years with memory concerns 13 (without diagnosed dementia) and inactive (doing <60 minutes of moderate or vigorous 14 intensity leisure activity a week) [20] with total minutes calculated from screening 15 questions that asked about PA type, duration, frequency and intensity.. Screening was 16 completed via telephone and also included: the Telephone Interview for Cognitive Status -17 Modified (TICS-M) [21], Geriatric Depression Scale 15 (GDS-15) [22] and Revised 18 Physical Activity Readiness Questionnaire (PAR-Q) [23]. Participants were included if they 19 answered "Yes" to the question "Do you have any difficulty with your memory?" They were 20 considered to have subjective cognitive decline (SCD) if they scored in the range of normal 21 control group scores for their age and sex on the Cognitive Battery of the Consortium to 22 Establish a Registry for Alzheimer's Disease (CERAD) [24]. In addition to a "Yes" 23 response to the above question participants who scored below the normal range on the 24 cognitive measure (CERAD) were defined as having MCI. 25

1 Exclusion criteria were: scoring less than 19 out of 50 on the TICS-M [21]; more than 5 on the 2 GDS-15; diagnosis of dementia; a Mini-Mental State Examination score (MMSE) < 24 [25]; unstable or life-threatening medical condition; medical condition contra-indicating moderate PA; 3 4 Body Mass Index (BMI) > 37; severe visual or hearing impairment; history of chronic alcohol abuse 5 within the past five years; not fluent in English and inability to attend follow-up visits. Classification of dementia reflected a score of <24 on the SMMSE or a TICS-M score of <19. Classification was 6 7 overseen by a diagnostic group led by a psychiatrist that considered functioning in addition to cognition. The participant's primary care doctor was asked to approve participation. 8

Participants were recruited from the Melbourne metropolitan area via web sites and newsletters,
memory clinics, seniors' groups and the media. The participants gave informed written consent to
participate and the Melbourne Health Human Research Ethics Committee approved the trial. The
study took place at the National Ageing Research Institute, Parkville, Australia.

13 The Physical Activity Intervention

Both groups received the same program of 150 minutes of moderate intensity PA per week 14 completed as 3 x 50-minute sessions or 5 x 30-minute sessions to allow for preference and 15 flexibility to fit in with the participant's routine. The program was progressive, taking up to 8 weeks 16 17 to reach the full duration of the sessions and moderate intensity (55-65% heart rate reserve). Intensity was monitored using the Borg Perceived Rate of Exertion scale (RPE 10-12) [26]. All 18 participants were given a manual containing the same information about progressive walking, 19 20 water walking, swimming and cycling programs and exercise safety. The manual also included an 21 individualized PA program with standardized diaries to record their PA. Diaries were returned 22 monthly by prepaid post. The program was home-based and unsupervised with monitoring via the 23 phone calls and diaries. Details of the program and demonstration of the PA including the 24 frequency, intensity and recording details of the PA in the diaries was outlined in the first face to 25 face workshop session by the same PA facilitator. The manual for the intervention group also included information on the goal setting. The control group were given copies of the 26 workshop slide presentations on the standard education topics. 27

1 Goal-Orientated PA and Mentoring Intervention Group

The objective of the Goal oriented PA program was to enhance PA self-efficacy and increase PA. 2 3 The Bangor Goal-Setting Interview (BGSI) [27] modified for use in INDIGO to focus specifically 4 on PA was employed for individual goal identification and goal setting. The interview conducted 5 by the same experienced PA facilitator focused on the 5 individual goals from the PA and PF 6 areas identified in the baseline BGSI. Participants selected 3 personal goals to operationalize and 7 work on during the intervention period. The intervention group's resource manual also included 8 information on setting SMART goals, the development of strategies to achieve behavior change, 9 practical aids and action plans to facilitate goal performance.

10 Intervention Group Workshops

11 The program content was delivered over the first 6 months via 3 face to face workshops

12 conducted by the PA facilitator and supported by the mentoring program.

The first workshop also attended by mentors was for 2 hours, with the content of the first hour 13 outlining the PA program, and a demonstration walk session. In the second hour, the intervention 14 15 group focused on identifying and prioritizing more specific PA goals, operationalizing goals and 16 strategies for goal performance. The 2 remaining 1-hour workshops were conducted at 8-weekly intervals. Topics included setting SMART goals; evaluating progress; feedback; getting the most 17 out of the mentoring process; identifying barriers to goal performance; developing practical aids to 18 19 overcome specific barriers; reassessment of goals; identification of effective and ineffective 20 strategies and review of the action plan. These topics were followed up during the mentor calls in 21 between the workshop sessions.

22 Mentor Telephone Contact Protocol

Each intervention group participant received 6 calls from their mentor at 4-weekly intervals starting at week 2, then weeks 6, 10, 14, 18 and 22 over the 6-month period. Participants were asked about their PA program progress, prompted to complete and return their PA diaries. Mentors used a semi-structured script and employed the techniques of reflective listening and spontaneous

1 discussion to engage participants in working on their relevant goals, gave feedback and discussed

2 strategies to on how to keep on track. They recorded the number and time spent on calls.

3 Control Group

4 Standard Education Program Workshops

The control group received a standard education program conducted over 3 workshops scheduled at the same intervals but on separate occasions to the intervention group. The first workshop was for 2 hours, also attended by the peer volunteers (PALS), with the content of the first hour outlining the PA program and a demonstration walk session. In the second hour the research staff gave a generic presentation on 'Healthy Ageing'. The other 2 workshop sessions were conducted as direct information giving sessions with no motivational content for PA and included topics such 'stress and depression' or 'enjoying retirement'.

12 PAL Telephone Contact Protocol

Participants received 6 scripted telephone calls from their peer volunteer (PAL) with the same
scheduling as the intervention group. PALS recorded number of calls, asked direct questions about
PA progress and prompted return of the PA diaries but did not give any feedback or motivational
advice.

17 The Peer Volunteer Program

Thirty-two physically active (meeting the PA guidelines of at least 150 minutes/week of moderate intensity PA [28]) adults aged 50-85 years were recruited from the community via volunteer support groups for seniors and the media in the Melbourne Metropolitan area. Assessments of PA and PA mentoring self-efficacy were completed at baseline, 6 and 12 months after each peer support period [19]. Post baseline peer volunteers were randomly allocated to be trained as either mentors or Physical Activity Liaisons (PALS).

Mentors attended an 8-hour face to face training course developed for the trial that focused
specifically on the content of the participant intervention program and skills training for the
development a motivational interviewing style of counseling. The PALS attended a 3-hour face to

- 1 face training course on the content of the control program only and how to deliver the standard
- 2 telephone contact to the control group without engaging the participants in any 'motivational talk'.
- 3 Over the period of the trial mentors and PALS were assigned to their respective
- 4 intervention/control participants via a systematic approach of sequenced lists of mentors/PALS and
- 5 participants. Both mentors and PALS were assigned to a research team member as a 'senior
- 6 mentor' who provided support via scheduled phone calls during the intervention.

7 Baseline Assessments

- 8 Following provision of written consent, baseline assessment covered health (height, weight, BMI),
- 9 a demographic health and lifestyle questionnaire (illness, injury, falls, medications), PA and fitness,
- a cognitive and clinical test battery and a saliva sample for apolipoprotein E epsilon 4 (APOE)
- 11 genotyping [19]. A goal-setting interview (the BGSI); [27] was conducted.

12 Physical Activity Assessment

- 13 Physical Activity Measurement
- Pedometers (Yamax CW-700/701 Digi-walker, Yamax Co., Japan) were worn by participants for 7 days to measure their PA. They recorded their daily steps and hours sitting in a diary. Any time during the waking hours that the pedometer was not worn was noted by the participant in a daily diary with the type of activity, time spent in and the intensity of any non-step activity, (eg waterbased activity) recorded. A step count for this activity was estimated based on 100 steps/minute for low moderate intensity (3 MET) and 200 steps/minute for moderate intensity activity e.g. swimming [29].

21 Physical Activity Questionnaires

The CHAMPS PA questionnaire recorded the frequency and duration of activities, with the caloric expenditure (kcals), and minutes per week spent in all, low, moderate, hard and very hard intensity PA calculated [30]. Moderate and vigorous PA (MVPA) from the CHAMPS questionnaire was determined as the sum of the moderate, hard and very hard PA.

- 1 Self-efficacy Questionnaires: PA Self-efficacy under adverse events (SEQ) was assessed on a 5-
- 2 item questionnaire using a 5-point Likert scale [31]. Participant's rating on a scale of 0-100% of
- 3 their confidence to complete a specific PA task (150minutes/week of moderate intensity PA) was
- 4 defined as program specific self-efficacy [32].

5 Fitness Assessment

- 6 Components of functional fitness were assessed using the following tests [33, 19].
- 7 Cardiovascular Fitness: the 6-minute Walk Test [34].
- 8 Lower Leg Strength: the Sit-to-Stand Test [35].
- 9 Mobility and Agility: the Timed Up and Go Test (TUG) [36].
- 10 Dynamic Balance Step Test: stepping one foot at a time on and off a 7.5 cm high step as many
- 11 times as possible in 15 seconds. [37].
- Grip strength: measured with a Smedleys hand dynamometer on the dominant and non-dominanthand [38].

14 PA Adherence

- 15 Adherence to the prescribed PA was determined from the return of self-reported PA diaries that
- 16 recorded the type, frequency, duration and intensity of the PA. Adherence to the prescribed study
- 17 PA program was defined as the number of minutes of moderate intensity PA completed relative to
- 18 the prescribed 150 minutes/week expressed as a percentage (ADH). Adherence to the prescribed
- 19 PA and any additional moderate intensity PA that the participants were already doing at baseline
- 20 was defined as total adherence (TotADH). This variable was included to determine if the
- 21 prescribed PA replaced previous habitual PA.

22 **Retention**

- 23 Retention rate was determined as the number of participants assessed at 6 and 12 months,
- 24 expressed as a percentage of the number of participants randomized.

1 Goal Performance and Goal Satisfaction Scores

2 The modified BGSI was also used as an outcome measure of goal performance and goal 3 satisfaction. In a face to face interview all participants discussed the areas of physical health (PH), 4 (PA), physical function (PF) and every-day function (EDF) identifying issues to form the basis of 5 goals. They identified 3-5 goals in the area of PF (e.g., strength, agility, fitness etc.) and/or PA 6 (type, frequency, duration etc.) and rated their current performance and satisfaction for each goal 7 on a scale of 1-10 (1=not able to do it/not satisfied at all and 10=able to do it extremely 8 well/extremely satisfied). A mean score for goal performance was calculated from the sum of the 9 individual goal ratings divided by number of goals set. The mean goal satisfaction score was 10 determined in the same way.

11 Only the intervention group operationalized their goals and continued to work on these during the 12 intervention.

13 Importance and Readiness to Change Behavior Scores

Self-rating on a scale of 1-10 of the importance and readiness to change behavior in the PF and
PA areas was determined at baseline only.

16 Cognitive and Psychological Assessment

- 17 A battery of cognitive, psychometric and neuropsychological tests was administered at baseline, 6
- and 12 months by an observer blinded to the participant's group allocation [19]. The Mini-Mental
- 19 State Examination (SMMSE), a measure of global cognition [25] and the Alzheimer's Disease
- Assessment Scale 13 cognitive section (ADAS-cog 13) [39] were used in the modelling in this
- 21 report to determine if baseline cognitive status influenced the PA results.

22 Follow-up Assessments

- 23 All baseline measures were re-assessed at 6 and 12 months except for the
- APOE4 genotyping for those recruited for 12 months. For those recruited for 6-months only
- assessments were at baseline and 6 months.

26 Program and Process Evaluation

1 After 6 and 12 months, participants completed a questionnaire specific to this study to provide 2 feedback on the program. Items were structured so that they answered "yes" or "no" for more general questions and then rated the item on a scale 1-5 with 1 being the least favorable and 5 the 3 4 most favorable score. Questions asked about enjoyment (eg. "How enjoyable did you find the PA 5 program?"), understanding (eg. "Did you find it easy to follow the program we set out for you?") and helpfulness (eg. "How helpful did you find.....?). Similarly, specific program components and 6 7 resources such as the PA program, the information manual, the goal-setting activities, workshops, mentor/PAL phone calls, perceived "knowledge", "understanding" and "motivation" shown by 8 9 mentor/PALS was evaluated. The latter 3 attributes were summed then expressed as a percentage 10 for a mentor/PALS total attributes score.

11 Workshop Adherence and Fidelity of the Peer Volunteer Support

Total number of attendances at 3 participant workshops was recorded with workshop adherence
 calculated as a percentage of workshops attended to workshops scheduled.

14 Peer volunteer support and fidelity of the phone calls was derived from the total number of successful

15 calls (as defined and recorded by the peer volunteer) the total time of the call and the mean call time.

16 Call compliance was defined as the percent of successful calls made compared to the number of17 scheduled calls.

18 Sample Size

19 We estimated that to detect a mean difference of 1200 steps/day between the groups at 80%

20 power, α = 0.05, 76 participants were needed for each group [19].

21 Randomization and Blinding of Observers

22 On completion of the baseline assessments participants were randomized to either a goal oriented

- and mentoring PA intervention group or control group according to a list of computer-generated
- random numbers in varying block sizes using the "ralloc" user-written command implemented in
- 25 Stata 12 statistical software [40] performed by an investigator not involved in the data collection.
- 26 Randomization was concealed in envelopes and an independent person completed the allocation

of participants to the intervention or control group. This was a single blind study where researchers
responsible for the cognitive and clinical assessments were blinded to the treatment allocation.

3 Statistical Analysis

4

Data were summarized using mean and standard deviation (sd), median and first to third quartiles 5 6 (Q1, Q3), or counts and proportions as appropriate. Pedometer scores; self-reported PA (all and 7 MVPA); adherence; cardiovascular fitness, balance, mobility (TUG), leg strength, grip strength; 8 goal performance and satisfaction; and self-efficacy were modelled using linear mixed models. All 9 models tested the time by group interaction to determine whether the change over time differed 10 between the two groups. Post hoc, pedometer scores and MVPA analyses assessed potential 11 confounders including (baseline age, sex, APOE4 status, body composition, fitness components, 12 cognition, importance and readiness to change PA, mean total goal performance and satisfaction, 13 self-efficacy, self-efficacy for a walking program, self-efficacy to complete 150minutes/week PA, and 6-months total and mean call time, enjoyment of the PA and phone calls) and the method of 14 15 backward elimination was used to arrive at an adjusted model. Post hoc marginal linear prediction contrasts are provided for changes over time where no group differences were detected. For 16 fitness measures, only age and sex were assessed as potential confounders 17 18 Baseline characteristics of the two study duration cohorts were compared and a sensitivity analysis where models were refitted with just the 12 month study cohort were conducted to ensure that 19 conclusions are consistent. 20

21

Given the exploratory nature of this trial, multiple adjustments have not been carried out. However,
we acknowledge that a considerable number of hypothesis tests have been conducted and as
such, caution should be exercised when interpreting significant (and non-significant)
results.Statistical modelling was performed using Stata v.15 (StataCorp LLC, College Station,
Texas) and statistical significance was set at a p-value < 0.05.

1 **RESULTS**

The participant flow through the study is shown in Figure 1. A total of 52 participants was assessed at baseline and randomized into the 2 study groups. The number of participants was lower than planned and extension of the recruitment period was limited due to funding restrictions. Thirty-six participants were followed for 12 months. A further 16 were recruited with follow-up truncated at 6 months. Participants who withdrew during the trial were invited to return for the follow-up assessments to allow for an intention-to-treat analysis.

8 **Baseline characteristics**

9 Participants' baseline characteristics are reported in Table 2a. Mean age (± sd) was 70.1 (6.4)
10 years with 33 (63.5%) of participants being female. The baseline characteristics of the participants

11 recruited for 6 and those recruited for 12 months are shown in Table 2b.

12 Mentor and PAL Characteristics

Thirty-two peer volunteers were recruited and trained with 7 (21.9%) withdrawing after randomization but before assignment to a participant, 20 (80%) completed 6 months of support and 19 (76%) completed 12 months. Mean age (\pm sd) (n = 25) was 65.8 (6.25) years, 15 (60%) were female. Both the mentors and PALS had excellent and similar telephone call-adherence 81.9 (70.4, 93.5)% and 87.2 (77.2, 97.1)% respectively. By design the total call time was higher for the mentors 107 (86.6, 127) minutes compared to PALS 56.7 (45.1, 62.3) minutes (p<0.001).

19 Retention of Participants

Two participants from the intervention group withdrew before the start of the intervention. A further 2 withdrew from the intervention during the first 6 months but returned for assessments. After 6 2 months the overall retention (return for assessment) was 88.5% (n = 46) with no significant 2 difference detected between the intervention and control group 84.6% (n = 22) vs 92.3% (n = 24) 2 respectively. For the participants who were in the sub-group for 12 months and were assessed at 2 12 months (n = 30) retention was 83.3% with no observed significant between group difference in 2 long-term retention 77.8% (n =14) versus 88.9% (n = 16) for the intervention and control group respectively Figure 1. However, although returning for follow-up 2 participants in the intervention
group discontinued the PA intervention during the first 6-months and another discontinued PA
during the second 6 months resulting in a total of 3 discontinuing the intervention over 12 months.
The main reasons for not continuing with the intervention or participation in the study (n = 9) over
12 months were "health" (n=5) (55.6%) and "no longer interested" (22.2%).

6 In the sub-group who were enrolled for 12 months, 9 (17.3%) withdrew from the study completely 7 or withdrew from the PA intervention resulting in a long-term participation rate of (n = 16) 88.9% in 8 the control group compared to (n = 11) 61.1% in the intervention group (p = 0.054).

9 Physical activity

10 Pedometer Scores

The pedometer scores of steps/day for both groups at baseline, 6 and 12 months are shown in
Table 3. There was no significant difference detected between the control and intervention groups
in the pattern of change in steps/day over time (p = 0.129).

14 In the secondary analysis there was a significant increase in mean steps/day (95% CI) for both groups over time at 6 months 1662 (943, 2383) steps/day (p < 0.001) and 1320 (603, 2037) 15 steps/day (p < 0.001) at 12 months. When baseline BMI and fitness (walk distance) were included 16 in a multivariable model, both were associated with a significant change in steps/day over time 17 18 (Figure 2(a)). On average, 1 metre more of baseline walk distance on the 6-minute walk test was associated with an increase of 14.6 (3.4, 25.7) steps/day (p = 0.010). Conversely, 1 unit increase 19 in baseline BMI was associated with a decrease of 228.7 (41.1, 416) steps/day (p = 0.017). The 20 21 model explains 34.4% of the variability in steps/day. The effect size for the total group, Cohen's f², 22 of 0.31 for time (the intervention) was medium to large. No associations with potential confounders such as age, sex, cognitive status, self-efficacy, study-time or APOE4 status were detected. Figure 23 2 shows the relationship of time and steps/day adjusted for baseline BMI and walk distance for the 24 whole group. 25

26 Self-Reported Physical Activity

The raw scores for minutes/week of time spent on all PA and MVPA for the study period are shown
in Table 3. For time spent on all PA no significant difference in change over time was detected
between the 2 groups (p = 0.082). During the second 6 months of the study the control group
continued to increase PA whereas the intervention group had a decline in the rate of change of PA.
No significant difference was detected between the 2 groups (p = 0.051).
For both groups combined however, total time spent in all PA increased significantly on average

220.2 (117.4, 323.1) (p = 0.001) minutes/week at 6 months and 274.5 (164.9, 383.9) (p<0.001)
minutes/week at 12 months.

9 Similarly, for MVPA, no significant difference in change over time was detected between the 2
10 groups (p = 0.082). A sensitivity analysis to assess the impact of the study-time, as for steps/day,
11 found conclusions to remain the same (p = 0.100).

12

The MVPA in the secondary analysis increased from baseline over time in both groups (p<0.001) 13 with the approximated mean increase of 165 (125, 210) minutes/week and 160 (102, 229) 14 15 minutes/week at 6 and 12 months, respectively, from the univariate model. In a multivariable 16 model, younger age at baseline was associated with the increase in MVPA over time (p = 0.002) as were higher baseline cognition (SMMSE) (p = 0.002), and higher baseline goal performance (p17 = 0.002). When the total time of the PALS/Mentors calls and the enjoyment rating of the PA 18 19 program over the first 6 months were entered into the model, there was evidence that the 20 relationship of call time to MVPA varied over time. Relative to 12 months, the call time had a 21 stronger positive effect on MVPA at 6 months (p = 0.021) demonstrating that higher total call time 22 in the first 6 months resulted in more MVPA undertaken in the intervention 6 months. Further, the 23 relationship of the enjoyment of the PA program with MVPA varied over time with the enjoyment at 24 6 months having a stronger positive relationship with MVPA at 12 months (p = 0.033). That is, the 25 more people enjoyed the PA program during the first 6 months the more MVPA they did in the 26 second 6 months. Figure 2(b) depicts the relationship of time and MVPA adjusted for baseline age, 27 SMMSE, goal performance score, 6 months call time and enjoyment rating for the whole group.

1 Adherence

2 Both groups achieved high ADH and TotADH (Table 4). Median (Q1-Q3) adherence rates of 87.4 3 (76.1 - 95.8)% versus 91.1 (71.7 - 95.7)% and 84.6 (78.5 - 92.9)% versus 84.8 (70.1 - 98.9)% for 4 the control and intervention groups during the 0-6 months and 6-12 months respectively with no 5 significant differences detected. Forty participants (81.6%) had greater than 67% ADH for the first 6 months with 23 (82.1%) maintaining this level during the 6-12 month period with similar numbers 6 7 in each group. The results for TotADH were consistent with these results for the ADH. ADH was 8 associated with higher baseline goal satisfaction and total call time during the 0-6 month period. One point on baseline goal satisfaction score was associated with a 6.6% increase in ADH (p = 9 10 0.012) and 10 minutes higher total call time was associated with a 1.9% increase in ADH (p =0.004). The PA intensity RPE for both groups was similar 10.8 (10.5, 11.2) versus 10.9 (10.4, 11.4) 11 12 for 0-6 months and 10.9 (10.3, 11.4) versus 11.0 (9.9, 12.0) for 6-12 months for the control and intervention groups, respectively. The PA of choice was walking n=48 (96%).

14 Fitness

13

15 No significant difference in the change over time was detected between the 2 groups for any of the 16 fitness measures (Table 5). However, for both groups combined cardiovascular fitness, mobility, 17 leg strength and balance but not grip strength improved significantly with the intervention (p < 10.001). These improvements translate to a mean increase in cardiovascular fitness of 18 19 approximately 7% and 10% after 6 months and 12 months respectively with corresponding 20 improvements in mobility 11% and 16%; leg strength 18% and 19%; balance 18% and 28%. 21 Women on average walked 56 metres less than men on the 6-minute walk test (p = 0.024) and older age was associated with lower mobility (p = 0.006). Being female and older was associated 22 with poorer grip strength (p<0.001) and (p = 0.017). No associations with age and sex were 23 detected with other fitness measures. 24

25 Goal Performance and Satisfaction

There were no significant differences detected between groups in the pattern of change in goal 26 27 performance and goal satisfaction over time. Goal performance scores for both groups combined increased significantly over time with on average increases of 3.80 (3.30, 4.30) and 4.00 (3.24,
4.75) (p<0.001) at 6 and 12 months respectively (Table 6). Goal satisfaction scores had a similar
pattern of change with increases of 4.12 (3.57, 4.67) at 6 months and 4.44 (3.63, 5.26) (p<0.001)
at 12 months.

5 **PA Self-efficacy**

No significant differences were detected between the groups for change over time in PA selfefficacy. For both groups combined PA self-efficacy increased on average by 2.66 (1.26, 4.06)
(p<0.001) and 1.83 (0.28, 3.39) (p = 0.025) over 6 and 12 months, respectively. PA program
specific self-efficacy was high at baseline for both groups 96.6 (94.2, 98.8)% and was maintained
over time 97.6 (95.0, 100.1)% and 97.3 (95.1, 99.5)% after 6 and 12 months, respectively.

11 Fidelity and Program Evaluation

The delivery, attendance and compliance with aspects of the program was high with similar mean attendance rates for the workshops, 97.4 (92.2, 102)% for the control and 85.9 (73.7, 98.0) for the intervention group. The control group had 96.2% and the intervention group 76.9% participants achieving a 100% attendance at the workshops (p = 0.074). Diligence in following up participants for calls (total attempted calls) was 6.69 (5.84, 7.53) calls for the PALS and 5.11 (4.02, 6.20) calls for the mentors.

18 At 6 months 24 control and 21 intervention participants completed the program evaluation guestionnaire. All respondents reported that the PA program was easy to follow and 95.6% 19 20 enjoyed their respective programs. The "enjoyment" rating of the PAL/mentor phone calls was high 21 and similar for both groups mean 3.49 (sd 1.27). Reasons why the calls were enjoyable included 22 'positive qualities' of the PALS/mentors (40%) and that they provided motivation and the opportunity to talk about issues (37%). The control group rated the perceived "understanding" 23 24 shown by their PAL 4.32 (0.57) which was significantly higher than the intervention group's rating 25 of 4.00 (0.66) for their mentor (p = 0.0005). Further, the "attributes of the PAL" score by the control group was 79.1% and "attributes of the mentor" score by the intervention group was 63.5%. 26

1 After 12 months in the program, 96.6% (n = 28) enjoyed the second 6-months with similar high 2 enjoyment ratings. Fifteen (93.8%) in the control and 10 (76.9%) in the intervention group continued with their prescribed PA. No longer receiving calls from their PALS/mentors was not 3 4 seen as affecting their ability to continue with their PA (reported by 93.8% (n = 15) of the control 5 and 91.7% (n = 11) of the intervention groups). Reasons given for why lack of calls did not affect PA was that PA was a routine or habit 50%, (n = 11) and that participants were now self-motivated 6 7 45.4% (n =5). Having PALS/mentors was still seen as important to promote PA in older adults by 82.8% (n = 24) of participants. 8

9 Injury during the PA Program

Bursitis in the hip was reported by 2 women in the control group during the first 6 months of the program. They missed 6 and 11 of their prescribed sessions respectively, but the bursitis resolved and they continued with their PA program for the 12 months.

13 DISCUSSION

In this target group of inactive, older adults at increased risk for cognitive decline we compared two 14 15 different approaches, a more intensive approach utilizing goal-setting and an active control, and 16 found both were effective with no significant differences between the groups detected. In this first study in this target group, although we were unable to realise the primary aim of the trial, by 17 combining the data from the two groups we were able to identify key factors salient to future efforts 18 19 to promote PA in underactive older people at risk for cognitive decline. Not being able to show differences between groups in peer-led PA interventions is not uncommon 20 21 [18]. In the current study, there were several possible reasons for this, the most evident being a 22 lack of power. Secondly, it is possible that the two approaches used were too similar either in 23 design or implementation. Table 1 highlights the similarities and differences between the programs

- and some design elements that may have been contributing factors. In terms of design, both
- 25 groups were asked to rate their goal performance and satisfaction as outcome measures. Also,
- both groups monitored their PA progress via their diaries and self-monitoring has been shown to
- be an effective technique to increase PA and MVPA [41, 42]. With respect to potential similarities

1 in study design, we had processes in place to minimize this, for example both the mentors and

2 PALS received training on their respective roles only and they were regularly advised and

3 supported by senior mentors to keep them on task.

Irrespective of not being able to discriminate between 2 intervention approaches, by combining the
groups and examining the changes over time for the outcomes and the factors that were
associated with these changes we were able to determine some relevant and novel findings that
are salient to the promotion of PA in this group of older adults.

8 *Effects of participation on physical activity*

9 Across the groups as a whole, participation in the intervention increased PA as determined from pedometer steps over time. This change in steps/day exceeded the 1,000 steps/day that has been 10 11 associated with a lower risk all-cause mortality cardiovascular disease morbidity and mortality [43] and frailty [44]. The magnitude of the change equates to 13-16 minutes/day or 92-117 12 minutes/week of brisk walking [45] and has important health implications. The PA levels in our 13 14 study reached more than 8,000 steps/day which exceeds the 7,100 steps/day as the minimal 15 amount recommended to achieve health benefits for older adults [46]. Further, in an earlier study in participants with MCI or SCD using the same 6-month PA program we demonstrated a 16 17 difference of approximately 1,285 steps/day that was associated with improved cognition when 18 compared to usual care after 6 and 18 months [6]. The association of higher baseline aerobic 19 fitness measured by the 6-minute walk and an increase in PA is not surprising [47] nor is the 20 association of higher BMI and lower levels of PA [48]. However, these results suggest that 21 modifiable risk factors, such as low fitness and overweight rather than age, sex, cognitive and 22 APOE4 status maybe the more relevant barriers to increasing PA in this target group. This highlights the need to identify those who are less fit and overweight and at risk of not achieving 23 increases in PA and to consider additional strategies to overcome these barriers in PA programs. 24 25 The medium to large effect size of the intervention to increase PA demonstrates that these participants were not only able to adopt a more active lifestyle and maintain this in the long-term 26 27 but that the magnitude of the change has potential health benefits.

This increase in PA was also supported by the increase in minutes/week of all intensities of PA as well as the MVPA for both groups. The significant increase in MVPA for both groups over 6 months of 164 minutes/week and 188 minutes/week for 12 months exceeds the recommended level of 150 minutes/week [28] and the target amount of PA for the PA intervention further supporting the efficacy and acceptability of the PA program.

6 It is possible that factors other than the intervention, may have played a part and been more potent 7 in determining the increase in PA and MVPA as seen with the association of conventional factors 8 such as age, cognition as well as program factors and MVPA in the multivariate model. The 9 observation that younger age, better cognition and higher goal performance at baseline were 10 associated with higher levels of MVPA is not unexpected as these characteristics would not only support a greater capacity to follow and perform the PA but also to accurately recall the PA for self-11 12 reports. Program factors were also associated with increases in MVPA namely more peer support call time over the 6-month intervention associated with greater increases in MVPA over 6 months 13 but not 12 months. As we reported significantly higher call time in the intervention group compared 14 to the control group it is possible that when the calls were ceased in the second 6 months this had 15 16 more impact on the intervention group than the control resulting in the declining rate of change in 17 MVPA for the intervention group and increasing MVPA for the control group over the second 6 months. Enjoying the initial 6 months of the program was important for the maintaining MVPA 18 during the second 6 months of this study. Both of these findings highlight the importance of 19 20 providing a positive experience for inactive older people when initiating a PA program to support 21 ongoing behavior change. This finding supports the emerging concept that enjoyment rather self-22 efficacy is a stronger predictor of increased PA [49, 50]. The results of our program evaluation showing high ratings of enjoyment of the PA program and the peer support calls demonstrate a 23 24 positive experience for both study groups with the enjoyment attributed to the PALS/Mentor 25 qualities and the motivation providing by being able to talk about issues. It is possible that these qualities, rather than differences in the content (education versus goal orientation) and delivery 26 27 style may have had a more potent effect on participation thus demonstrating that different 28 strategies can achieve good results.

1 Other interventions using peer-led delivery did not establish a difference between groups in PA in 2 the short term. In a 4-months PA intervention utilising a group-mediated behavioral intervention with goal-setting with peer advice and support versus a standard community PA promotion and 3 4 education both groups had similar increases in PA. However, after 18 months follow-up the peer-5 led group had better PA results compared to the standard group [17, 51]. Our study differed from 6 that of Floegel and colleagues [51] in that it was home-based, the peer support was via telephone 7 contact and the follow-up was at 12 months. Our mentors may not have been as interactive thus 8 not achieving the same levels of social connectedness and social support that may partly explain 9 the difference in the long-term results.

10 Adherence to the Physical Activity Program

11 The 79% mean adherence rate for the whole group was similar to that observed in our previous studies with similar target groups [7, 8]. The observation that adherence did not change with time is 12 also similar to our previous study where adherence to the same home-based program was 13 14 consistent over 24-months demonstrating that this type of program is acceptable and sustainable 15 in the long-term for this target group. The current study results are even more remarkable given that the participants were inactive at baseline. These results are also comparable to other PA 16 interventions in those with MCI as a recent meta-analysis reported a 70% mean adherence rate 17 [52]. Only one study in this review reported adherence after the end of the intervention with only 18 19 25% continuing exercise after the end of the intervention [53] whereas in the current study over 82% of participants achieved more than a 67% adherence rate underscoring the success of the 20 study to motivate participation. The similar RPE scores for both groups within the range of 21 22 moderate intensity and the high retention and adherence rates provide further evidence that this 23 level of moderate intensity PA is both feasible and acceptable for this target group. Evidence that the program was adequately resourced and aimed at the appropriate level was demonstrated by 24 the response of 100% of participants that it was easy to follow and high ratings of enjoyment and 25 26 program components. This finding supports the suggestion from recent research that factors such

as enjoyment may be more relevant than traditional factors such as self-efficacy [Lewis et al 2015]
in motivating an increase in PA.

The program was also shown to be safe for this target group. Low-level bursitis was reported by
two participants, but was resolved and these participants continued with the program without
further incident.

6 During the initiation stage of the intervention, that is the first 6 months, having a higher baseline 7 goal satisfaction score was associated with higher adherence. Identifying participants with low goal 8 satisfaction scores and targeting these specific goals at baseline may be a potential strategy to 9 enhance adherence and increase PA. As noted there was a significant difference in total call time, with the intervention group having a significantly higher total call time than the control group. 10 11 However, the association of call time with adherence was independent of the group assignment. 12 This further supports the notion that contact time rather than the content of the contact may be a 13 more influential factor in increasing adherence at least in the initiation of PA. The belief of 92% of 14 participants that no calls during the second 6-month period would not affect their adherence, that 15 they were in a routine and were self-motivated was borne out by the maintenance of the adherence during the second 6 months. This suggests that peer-support is more critical in the adoption phase 16 of a PA intervention. 17

18 Effects on Functional Fitness

19 As the adherence to the program was similar in both groups this was reflected in similar gains in 20 fitness for both groups. Apart from grip strength we demonstrated significant and substantial short 21 and long-term changes in cardiovascular fitness, leg strength, mobility and balance which are 22 consistent with improvements of 7-46% in functional fitness reported in a review of health benefits 23 of aerobic PA in aged adults [1]. The magnitude of the change seen in the current study was 24 greater than the improvements in cardiovascular fitness (10% versus 4% and leg strength (19% 25 versus 10%) in our previous study after 12 months in a more active group using the same PA 26 program [8]. Further, the improvement seen in mobility measured with the TUG score was within 27 the range considered clinically significant (0.8-1.4 seconds) [54] This finding of improvements in

functional fitness is contrary to the conclusion from a meta-analysis that peer-led PA interventions in older adults may not be as effective in gaining improvements in functional fitness [55]. From the meta-analysis in 13 out of 18 studies the peers led the PA sessions and 5 studies delivered support in a similar manner to our program. In our study the PA program was set by the research staff for both groups and the peer support was mainly for delivery of the behavior change aspects of the intervention that is the goal orientation or education program. This may partly explain why in this specific target group we were able to demonstrate meaningful changes in functional fitness.

8 Goal Performance and Goal Satisfaction

9 Study participants increased their goal performance and goal satisfaction scores significantly over the course of the study with both groups showing similar improvements. The magnitude of the 10 mean change in goal performance of 4.00 and 4.44 for goal satisfaction over 12 months was 11 consistent with results achieved with cognitive rehabilitation in early dementia [56] and higher than 12 the goal performance scores seen when individual goals are targeted in therapy [14]. Further, 13 14 when mentoring was added to goal setting additional benefits in PA, body composition, global 15 cognition and memory were achieved compared to goal setting alone in healthy individuals at risk of dementia [13]. 16

17 Although we were able to demonstrate these significant gains in goal scores we were unable to 18 demonstrate a superior effect of the goal orientated intervention. As both groups completed the 19 BGSI and selected specific goals related to PA and PF and both then completed the same PA 20 program, it is possible that this exposure for the control group with peer contact was sufficient to 21 promote an increase in goal performance and satisfaction scores of similar magnitude in both 22 groups. The similar results for PA, adherence and fitness scores for both groups supports this notion. A further reason for lack of discrimination in these results could be that the PALS were 23 24 more engaging with the participants than the mentors. The PALS were trained to only ask direct 25 questions about PA progress, not engage in any motivational talk and their calls times were lower than the mentors. It is possible that the participants may have found this approach just as engaging 26 and more preferable as the control group seemed to relate more positively to the PALS rating them 27

higher on understanding and positive support for the program than did the intervention group for
their mentors. The control group also found their program information more helpful and were more
engaged in the education with better attendance at the workshops. Further both groups were
asked to record their PA sessions in PA diaries and self-monitoring is a strong motivator for PA
behavior change [57; 10]. Thus, similarities between the approaches and program factors may
have contributed to our inability to discriminate between the approaches.

7 Strengths and Limitations

A major strength of this study is that we targeted an under-researched at-risk group of inactive 8 9 older adults to increase PA with an established PA program and a validated goal orientation program. The modifications to the goal orientation program where the goals targeted specific 10 elements of PA allowed the participants to be more focused in their goal setting and actions was a 11 further strength. The use of the pedometer to objectively quantify the total daily amount of 12 ambulatory PA [46] was a strength but also a limitation as it may not have detected very low or 13 slow PA nor did it not provide a measure of the PA intensity. While the CHAMPS questionnaire 14 15 enabled us to record PA and estimate the PA intensity, the reliance on self-reported PA in this target group may potentially have been a limitation. The inclusion of program evaluation guestions 16 allowed for exploration of program factors that may have influenced behavior change and the 17 outcomes of interest. The similarity between the approaches discussed above was a limitation of 18 19 the study. This together with slow recruitment, resulting in low numbers of participants in the trial and thus reduced power, were limitations in enabling us to demonstrate between-group 20 differences. The further restriction in numbers with only a sub-group continuing for 12 months 21 limited our ability to demonstrate long-term changes. 22

In summary, in this inactive target group who are particularly difficult to engage we have provided
clear evidence that PA levels and functional fitness can improve and that after an initial stage with
peer support the PA can become habitual if it is enjoyable. These improvements were
commensurate with health benefits and this increase was achieved even with a less intensive
intervention. If these results are substantiated in future studies this has implications for PA

1 promotion in that fewer community resources may be needed which may lead to more cost-2 effective programs. Also, this less intense approach provides another option that researchers and practitioners can utilize in research or implementation programs where some individuals may do 3 4 better with one approach or another. Hence, having a range of effective options and providing 5 individuals with a choice to select what suits them best may potentially enhance the uptake of PA. Further, community peer volunteers successfully delivered and provided acceptable, effective 6 7 support for this target group and as such their value as a resource and delivery strategy should be economically evaluated. Barriers to participation identified in this study such as being overweight or 8 9 having low fitness levels should be a focus of future programs with the development of strategies 10 to overcome or minimize these. We have also highlighted novel theoretical constructs in the promotion of PA uptake and adherence such as enjoyment particularly in the initial stages and 11 program factors including social support provided by the peer volunteers. This support was 12 provided predominantly via phone but other forms of communication deserve exploration such as 13 emails and online social media. These findings have implications for translation into the community 14 and should be explored further to ensure that intervention strategies are relevant to this target 15 group. Due to the limitations outlined above these results are somewhat tentative until confirmed 16 17 in a larger adequately powered intervention study. Recruitment is challenging for such studies and innovative strategies may be required to attract participants. We further recommend that future 18 studies be conducted where the intervention is distinctly different from the control condition and 19 20 avoids or minimizes any overlapping methods.

21

22 CONCLUSION

In this inactive target group at risk of cognitive decline, no differences were detected between
groups in PA uptake hence we were unable to confirm our hypothesis that the novel PA
intervention utilizing individual goal-setting and peer mentors was superior to the control program.
Instead, both approaches were highly effective in increasing PA and fitness in the short and longterm. Our study demonstrates that programs supported by peer volunteers are acceptable and

- 1 effective and the findings suggest the less intensive peer contact maybe sufficient to improve PA
- 2 levels. This approach should be explored in larger targeted implementation studies.

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12 CONFLICT OF INTERESTS /DISCLOSURE STATEMENT

- The following authors have no conflict of interest to report (KC, EC, KE, LC, CE-B, LF, OA, DA, DL,
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- 15

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Table 1. A comparison of the similarities and differences between the program

components of the 2 study groups in the INDIGO study conducted in Melbourne, Australia.

Component	Control Group	Intervention Group	Comparison
Assessment of PA and	Pedometer.	Pedometer.	Same
Fitness	CHAMPS Q	CHAMPS Q	
	Fitness test battery	Fitness test battery	
Training course for Peer	3 hours PALS	8 hours Mentors	Different
Volunteers	Program content	Program content	
	Skills training in	Skills training in goal	
	direct questions	orientation program	
		and MI delivery	
Physical activity	150 mins/week	150 mins/week	Same
program	moderate intensity	moderate intensity	
	PA	PA	
Hard copy of Manual	PA Program	PA Program	Same
with Program	information and	information and	
	instruction	instruction	
Hard copy of Manual	Presentation slides	Goal orientation	Different
Group specific	on 'Healthy Ageing'	information and	
information		worksheets	
Number of Face-to face workshops	3	3	Same
Workshop 1		Part 1	Same
Content & Delivery	Part 1	Instruction on PA	
	Instruction on PA	program &Trial walk	
	program &Trial walk	Part 2	Different
	Part 2	Identifying and	
	'Healthy Ageing'	refining PA Goals	
	Lecture	Interactive	
Workshop 2 & 3	'Stress and	Goal-setting	Different
Content & Delivery	depression'	operationalization	
	'Retirement'	and skills	
	Lectures	Interactive	

Workshop Facilitator	Different facilitator	Same facilitator for	Different
	for each topic	all workshops	
Telephone calls	6	6	Same
number	Weeks 2, 6, 10, 14,	Weeks 2, 6, 10, 14,	
	18 and 22	18 and 22	
Telephone calls	Report PA	Report PA	Different
Content and delivery	Direct questions	Goal orientation	
	from PAL	MI style interactive	
		by mentor	
Recording of PA	Self-report of PA	Self-report of PA	Same
Adherence	Diaries	Diaries	
PA Goals Assessment	BGSI at baseline, 6	BGSI at baseline, 6	Same
	& 12 months	& 12 months	
	& 12 months Same interviewer	& 12 months Same interviewer	
Identification and	& 12 months Same interviewer None	& 12 months Same interviewer 3 out of 5 Goals	Different
Identification and Operationalizing PA	& 12 months Same interviewer None	& 12 months Same interviewer 3 out of 5 Goals identified,	Different
Identification and Operationalizing PA Goals	& 12 months Same interviewer None	& 12 months Same interviewer 3 out of 5 Goals identified, prioritized,	Different
Identification and Operationalizing PA Goals	& 12 months Same interviewer None	& 12 months Same interviewer 3 out of 5 Goals identified, prioritized, developed, actioned	Different
Identification and Operationalizing PA Goals	& 12 months Same interviewer None	& 12 months Same interviewer 3 out of 5 Goals identified, prioritized, developed, actioned and reviewed at	Different
Identification and Operationalizing PA Goals	& 12 months Same interviewer None	& 12 months Same interviewer 3 out of 5 Goals identified, prioritized, developed, actioned and reviewed at workshops and calls	Different

CHAMPS Q - Community Healthy Activities Model Program for Seniors Questionnaire, MI denotes Motivational Interviewing, BGSI - Bangor Goal-Setting Interview.

Table 2a. Baseline demographic, health and PA characteristics of participants in the 2

2

study groups in the INDIGO study conducted in Melbourne, Australia.

	Control Group	Intervention Group
	(n = 26)	(n = 26)
Age (Years)	68.5 (6.5)	71.9 (5.9)
Sex (n, % Females)	19 (73.1)	14 (53.8)
Education (Years)	14.7 (3.6)	15.3 (3.4)
Married/co-habit (n, % of group)	18 (69.2)	18 (69.2)
Retired (n, % of group)	20 (76.9)	21 (84.0)
SMMSE (range 24-30)	28.8 (1.6)	28.7 (1.7)
ApoE4 carrier (n, % of group)	6 (23.1)	12 (46.2)
Body Mass Index (kg·m ⁻²)	28.8 (4.6)	26.9 (4.4)
Overweight/Obese (n, % of group)	20 (76.9)	14 (53.8)
Ever smokers (n, % of group)	8 (30.8)	10 (38.5)
Pedometer score (steps/day)	6304 (2452)	7693 (3595)
MVPA (mins/week) Median (Q1-Q3)	15 (0 - 60)	30 (0 - 105)
Low Active (n, % of group)	25 (96.2)	23 (88.5)
Barrier Self-efficacy	15.1 (4.9)	16.6 (5.6)
Importance of PA change	8.7 (1.1)	8.6 (1.3)
Readiness to change PA	8.6 (1.4)	7.7 (1.7)
Falls history last 6 months (n (%))	7(26.9)	8 (30.8)

3 Values are mean and (sd), unless described otherwise. SMMSE denotes Standardized Mini-Mental

4 State Examination score. 'Low active' is the number of participants completing less than 150

5 minutes moderate or vigorous PA (MVPA) /week on the CHAMPS score. Overweight/Obese is

6 defined as BMI >25

	6 Month Cohort	12 Month Cohort
	(n = 16)	(n = 36)
Control Group (n, % of group)	8 (50)	18 (50)
Intervention Group (n, % of group)	8 (50)	18 (50)
Age (Years)	73.2 (74.5)	68.9 (5.1)
Sex (n, % Females)	9 (56.3)	24 (66.7)
Education (Years)	14.7 (3.9)	15.2 (3.3)
SMMSE (range 24-30)	28.8 (1.6)	28.8 (1.7)
ADAS-cog 13	11.7 (6.8)	10.5 (5.8)
Body Mass Index (kg·m ⁻²)	28.2 (1.3)	27 7 (1 7)

28.2 (4.3)

7283 (3260)

442 (337-622)

0 (0-45)

465 (106)

7.2 (1.9)

41.6 (20.2)

27.7 (4.7)

6893 (3123)

442 (300-750)

30 (0-105)

457 (71.4)

6.6 (1.3)

42 (18.2)

Table 2b. Baseline characteristics of participants in the cohorts recruited for 6 and 12

Values are mean and (sd), unless described otherwise. SMMSE denotes Standardized Mini-Mental State Examination score. section (ADAS-cog 13) denotes Alzheimer's Disease Assessment Scale

5 13 - cognitive. MVPA is defined as Moderate and vigorous intensity PA

Pedometer score (steps/day)

Walk Distance (m)

Timed Up and Go (secs)

All PA (mins/week) Median (Q1-Q3)

MVPA (mins/week) Median (Q1-Q3)

Self-efficacy for the walking program (%)

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Physical Activity	Control Group	Intervention Group	Total	Time x Group
				Interaction p value
Pedometer PA (steps/day)				
Baseline	(n = 24)	(n = 25)	(n = 49)	0.129
	6304 (2452)	7693 (3595)	7012 (3136)	
6 Months	(n = 23)	(n = 20)	(n = 43)	
	7954 (2868)	9305 (3190)	8582 (3062)	
12 months	(n = 16)	(n = 14)	(n = 30)	
	8517 (3170.6)	7670 (2995)	8122 (3067)	
Self-reported All PA (mins/week)				
Baseline	(n = 26)	(n = 26)	(n = 52)	0.051

Table 3. PA levels at baseline, 6 and 12 months for the two groups in the INDIGO study conducted in Melbourne, Australia.

(Median, Q1-Q3)	368 (225 - 675)	458 (375 - 750)	443 (308 - 698)	
Mean (SD)	491 (346)	569 (275)	530 (312)	
6 Months	(n = 23)	(n = 22)	(n = 45)	
(Median, Q1-Q3)	720 (450 - 990)	743 (465 - 1140)	720 (465 -1020)	
Mean (SD)	698 (310)	793 (391)	744 (351)	
12 Months	(n = 16)	(n = 14)	(n = 30)	
(Median, Q1-Q3)	923 (623 - 1133)	593 (405 - 915)	818 (495 – 1110)	
Mean (SD)	888 (328)	687 (375)	794 (359)	
Self-reported MVPA (mins/week)				
Baseline	(n = 26)	(n = 26)	(n = 52)	0.082
(Median, Q1-Q3)	15 (0 – 60)	30 (0 – 105)	30 (0 – 105)	
Mean (SD)	39.2 (57.2)	59.4 (77.9)	49.3 (68.4)	

6 Months	(n = 23)	(n = 22)	(n = 45)
(Median, Q1-Q3)	210 (105 – 240)	210 (105 - 255)	210 (105 – 240)
Mean (SD)	2134 (132)	212 (31.7)	213 (130)
12 Months	(n = 16)	(n = 14)	(n = 30)
(Median, Q1-Q3)	218 (105 - 428)	203 (105 - 240)	210 (105 - 255)
Mean (SD)	286 (243)	183 (107)	238 (196)

2 MVPA denotes (moderate and vigorous intensity PA). Values are raw scores of mean and (±sd) or median scores and (Q1-Q3) where noted.

3 The p value is from the univariable model and reflects the Time x Group interaction p value that tests for a difference over time for the 2 groups.

Table 4. Results for ADH and TotADH for the two 6-months periods and the overall 12-month period for the two groups in the INDIGO study

2 conducted in Melbourne, Australia.

Adherence	Control Group	Intervention Group	Total	Time x Group
				Interaction p value
Adherence to prescribed PA (ADH)				
0-6 months	(n = 26)	(n = 23)	(n =49)	
Mean (± SD)	79.1 (26.4)	79.4 (26.8)	79.3 (26.3)	0.798
(Median, Q1-Q3)	87.4 (75.1- 95.8)	91.1 (71.7 – 95.7)	88.88 (74.4 - 95.7)	
6-12 months	(n = 16)	(n = 12)	(n = 28)	
Mean (± SD)	81.7 (16.0)	82.8 (16.5)	82.2 (15.9)	
(Median, Q1-Q3)	84.6 (78.5 – 92.9)	84.8 (70.8 – 99.0)	84.6 (73.9 - 95.4)	
0-12 months	(n = 18)	(n = 15)	(n = 33)	
Mean (± SD)	82.1 (17.7)	76.2 (21.0)	79.4 (19.2)	

(Median, Q1-Q3)	87.8 (78.6 - 93.1)	85.0 (64.2 – 91.7)	85.8 (69.9 – 92.1)	
Adherence to prescribed & usual PA				
(TotADH)				
0-6 months	(n = 26)	(n = 23)	(n = 49)	0.909
Mean (± SD)	77.7 (26.8)	78.9 (27.1)	78.2 (26.6)	
(Median, Q1-Q3)	85.8 (72.3 – 96.0)	91.1 (69.5- 95.7)	85.8 (74.2 – 95.7)	
6-12 months	(n = 16)	(n = 12)	(n = 28)	
Mean (± SD)	80.8 (15.7)	82.0 (17.0)	81.4 (16.0)	
(Median, Q1-Q3)	84.2 (69.6 -92.9)	84.4 (69.3- 99.0)	84.2 (69.8 – 95.4)	
0-12 months	(n = 18)	(n = 15)	(n = 33)	
Mean (± SD)	80.9 (18.3)	75.5 (21.3)	78.5 (19.6)	
(Median, Q1-Q3)	87.8 (67.6 – 93.1)	84.7 (60.6 – 91.7)	85.6 (64.2 – 92.1)	

- ADH denotes (% Adherence to prescribed program), TotADH denotes, (%Total PA adherence). Values are unadjusted mean (±sd), median scores and (Q1-Q3). The p value from the univariable model and reflects the Time x Group interaction p value that tests for a difference over time for the 2 groups.
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Fitness Component	Control Group	Intervention Group	Time x Group
			Interaction p value
6-minute walk distance (m)			
Baseline	(n = 26)	(n = 26)	0.732
	454 (422, 486)	469 (436, 501	
6 Months	(n = 23)	(n = 20)	
	492 (456, 528)	499 (463, 536)	
12 months	(n = 16)	(n = 14)	
	507 (471, 543)	510 (468, 552)	
Timed Up and Go (TUG) (secs)			
Baseline	(n = 26)	(n = 26)	0.581
	6.97 (6.35, 7.59)	6.66 (6.15, 7.16)	
6 Months	(n = 23)	(n = 22)	
	6.06 (5.64, 6.49)	6.00 (5.55, 6.45)	
12 Months	(n = 16)	(n = 14)	

Table 5. Cardiovascular fitness, mobility, leg strength, balance and grip strength results over the intervention period for the control and

	5.79 (5.29, 6.29)	5.55 (5.03, 6.07)	
Sit to Stand (strength) (secs)			
Baseline	(n = 26)	(n = 26)	0.338
	10.9 (9.55, 12.3)	10.5 (9.44, 11.5)	
6 Months	(n = 23)	(n = 22)	
	8.70 (7.74, 9.60)	8.92 (7.91, 9.92)	
12 Months	(n = 16)	(n = 14)	
	8.84 (7.66, 10.0)	8.28 (7.37, 9.19)	
Balance Step Test (steps)			
Baseline	(n = 26)	(n = 26)	0.714
	14.2 (12.7)	14.4 (13.1, 15.8)	
6 Months	(n = 23)	(n =22)	
	17.1 (15.6, 18.6)	16.7 (15.4, 17.8)	
12 Months	(n = 16)	(n =14)	
	18.6 (16.9, 20.4)	17.9 (16.4, 19.3)	
Grip Strength (dominant hand) (kg)			
Baseline	(n = 26)	(n = 26)	0.653

		28.8 (26.7, 31.0)	29.8 (27.5, 32.2)				
	6 Months	(n = 23)	(n = 22)				
		29.4 (26.8, 32.0)	29.9 (27.6, 32.1)				
	12 Months	(n = 16)	(n = 14)				
		29.5 (26.7, 32.2)	29.2 (26.6, 31.9)				
3	Values are raw scores of mean and 95% (CI). The p value is from the univariable model and reflects the Time x Group interaction p value						
4	that tests for a difference over time for the 2 groups.						
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- 1 **Table 6.** Mean goal performance and goal satisfaction results over the intervention period for the control and intervention groups in
- 2 the INDIGO study conducted in Melbourne, Australia.

	Control Group	Intervention Group	Time x Group Interaction p value
Goal Attainment (1-10)			· · ·
Baseline	(n = 26)	(n = 26)	0.533
	2.84 (2.35, 3.33)	2.96 (2.49, 3.44)	
6 Months	(n = 23)	(n = 20)	
	6.52 (5.82, 7.22)	6.88 (6.31, 7.45)	
12 Months	(n = 16)	(n = 14)	
	7.01 (5.90, 8.11)	6.78 (5.67, 7.90)	
Goal Satisfaction (1-10)			
Baseline	(n = 26)	(n = 26)	0.914
	2.58 (2.10, 3.05)	2.61 (2.17, 3.04)	
6 Months	(n = 23)	(n = 20	
	6.60 (5.76, 7.43)	6.83 (6.25,7.41)	
12 Months	(n = 16)	(n = 14)	
	6.98 (5.79, 8.18)	7.09 (5.97, 8.21)	

3 Values are raw scores mean and 95% (CI). The p value is from the univariable model and reflects the Time x Group interaction p value that

4 tests for a difference over time for the 2 groups.

- **Figure 1.** INDIGO study participant flow from recruitment to the end of the 12-month
- 2 follow-up

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- **Figure 2 a.** Predictions of steps per day for all participants over time adjusted for
- 2 baseline BMI and fitness (walk distance) with 95% CIs.



- Figure 2 b. Adjusted predictions of Moderate and Vigorous PA (MVPA) minutes a week
 for all participants over time with 95% CIs. The model was adjusted for baseline age,
 SMMSE, mean goal performance score, the time interaction and 6-month call time and
- 4 the time interaction and 6-month enjoyment score.

