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Randomised trial of domiciliary versus centre-based rehabilitation: Which is more effective in reducing falls and improving quality of life in older fallers?

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### **Abstract**

## **Background**

To compare the effect of two modes of delivering a falls prevention service in reducing the rate of falls and improving quality of life, activity levels and physical status amongst older adults with a history of recent falls.

## **Methods**

A randomised controlled trial was conducted with a total of 107 subjects with blinded baseline and follow-up assessments. The participants were older community dwelling adults referred for a falls prevention service located in Brisbane, Australia. The intervention was a multiple component falls prevention service delivered in either in a domiciliary or centre-based mode of delivery. Both programs were similar apart from setting, and consisted of three components, a balance and strength component, falls prevention education and functional tasks. Physical and psycho-social assessments were administered at baseline, 8 week follow-up and 6 month follow-up. Falls data was collected by monthly telephone contact and by interview at 8 weeks and 6 months.

#### Results

The centre based service demonstrated significantly better results in preventing falls over the home based service. Clients in the centre based arm of the trial experienced fewer total falls and this group also had a greater reduction in the total number of fallers after the intervention.

## **Conclusion**

This research demonstrates that delivering a similar service in different settings – home based or centre based, impacts upon the effectiveness of the service. Community-Rehabilitation of fallers: home versus centre

dwelling older adults with a history of falls should be provided with centre-based programs in preference to home-based programs where they are available.

# **Key Words**

Falls

Frailty

Community Rehabilitation

## Introduction

Falls in older adults are a major physical, social and economic burden to both the individual and society as a whole. Multidisciplinary falls prevention services in the community aim to address the multiple factors that lead to physical decline and falls and return people to their normal activities. A recent systematic review and meta-analysis of interventions to prevent falls in the community includes 111 studies and concludes that multiple-component group exercise, Tai Chi and individually prescribed home exercise programs have been proven to reduce the rate of falls and risk of falling <sup>1</sup>.

Falls interventions described in the literature have looked at many different aspects of falls prevention and include interventions provided in either a home or a centre / group format. However, no head to head comparison of which setting is the more effective – home or centre – has been identified in older community dwelling adults. It is important to determine which of these settings is the more efficacious method of service delivery and which is the more cost-effective so that maximum value for limited health care inputs can be obtained. One trial has previously compared home training to a combination of home and centre based settings <sup>2</sup>. This study with a comparable patient population found improvements in the mental health component of the SF-36 and ambulatory capacity measured by walking speed and number of walks outdoors in the combination home / centre-based program over the home based program. No differences were found in falls rates between groups or other physical measures.

For centre based interventions, the stepping on program, a multifaceted community approach using small-groups reduced falls by 31% <sup>3</sup>. An intervention including group based exercise, vision management and home hazard reduction; found that the exercise program was the most potent single intervention and that the combination of all three interventions was the most effective at reducing falls <sup>4</sup>. A weekly community based group exercise has been shown to reduce falls by 40% versus a control group of no exercise over a 12 month period <sup>5</sup>. For home based interventions, a variety of exercise programs in different patient groups have had positive effects in reducing falls versus a control or usual care group <sup>6-8</sup>.

Even if both services are equally effective in preventing falls and improving quality of life, there may be economic advantages in conducting a service at home or in a centre. It is commonly believed that centre based therapy offers cost reductions for the health provider due to increased throughput of patients per staff member and transferring transport costs to the consumer. A recent break-even analysis of community rehabilitation falls prevention services found that whilst both home based and centre based services were able to break-even and thus be worth implementing from a societal perspective. The centre-based service however offered better value for money due to lower variable costs associated with providing the service <sup>9</sup>. Another study comparing home to day hospital rehabilitation following hospital discharge, found that while both groups recorded significant improvements in all functional measures from baseline at three months, the day hospital group was twice as likely to be re-admitted <sup>10</sup>. The authors of this study postulated that the differences in admission could possibly be due

to factors such as increased access to medical staff for the day hospital group and / or

increased mastery and self-management in the home based group and suggested that

home rehabilitation should be offered ahead of day rehabilitation services.

**Objectives** 

To compare whether a falls prevention service delivered either at home or in a group

setting is better for improving falls rates and health related quality of life. In addition,

activity levels, balance and strength measures and carer strain as secondary outcomes

of interest will be compared between the two settings.

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Methods

Design

Randomised clinical trial with blinded assessment at baseline, 8 week and 6 months

follow up. Participants were allocated to one of two groups, a domiciliary (home based),

individual community rehabilitation service or a centre based (hospital gym), group

community rehabilitation service. Comprehensive details of the methodology of this trial

have been previously reported <sup>11</sup>.

Participants and setting

Participants were community dwelling older adults aged >60 years who were referred to

the Metro South Community Rehabilitation Service by one of three local hospital

emergency departments (presented following fall but not admitted) or by their general

practitioner for falls or unsteadiness. Subjects were eligible for the trial if they were

referred to the service for falls or functional decline, were aged 60 years and over and

were able to complete a timed up and go test. Participants were excluded if they resided

in high level care, were non ambulant or were assessed by an Occupational Therapist

or Physiotherapist as being unable to participate in a community program due to

cognitive or physical function.

Interventions

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The program was a multiple intervention as defined by the Prevention of Falls Network Europe ( ProFaNE) <sup>12</sup> with a fixed combination of interventions delivered to all participants. These interventions were selected according to best available evidence <sup>1</sup> <sup>13</sup>, demonstrating the effectiveness of similar programs in preventing falls, and included exercise, home safety assessment and education components. Both groups received an eight week program delivered once a week and a home exercise program of three exercises tailored to the client's ability was given by a physiotherapist. The exercises were balance specific (e.g. tandem stance eyes open / eyes shut) and were to be performed twice daily for around 10 minutes each session.

Both programs consisted of three components, a balance and strength component, education and functional tasks. In addition all participants received recommendations for home modifications by an occupational therapist <sup>14</sup>. The centre based balance and strength component consisted of a warm-up of modified Tai Chi <sup>15-17</sup>, balance workstations, indoors walking circuit and lower limb strengthening exercises <sup>3 4</sup>. The home program was identical apart from substituting outdoors walking for the indoor walking circuit and activities of daily living for the upper limb circuit. Education was identical in both groups and consisted of 30 minutes of verbal presentation from the treating therapist (occupational therapist or physiotherapist) with handouts. The information covered falls prevention, promoting physical activity, goal setting and review, medication management, continence, relaxation, stress management and accessing community services similar to that used in previous studies <sup>18 19</sup>. In the centre-based intervention, functional training was conducted in standing and included

shoulder arc, peg board, climbing board and putty exercises. In the home based program functional tasks included cooking, hanging out washing and cleaning.

#### **Primary outcome measures**

Falls after the intervention commenced were collected monthly by telephone contact and at interview at the 8 week and 6 month follow-up assessments. The number of falls in the previous six months prior to the intervention was recorded by retrospective recall from the client at the initial assessment. Health related quality of Life was collected using the European quality of life tool (EQ-5D), a widely used, reliable and validated tool for measuring quality of life in similar populations <sup>20 21</sup>.

## Secondary outcome measures

Demographic and health assessments contained within the Ongoing Needs Inventory<sup>22</sup> (ONI) were used to collect demographic data and basic health data (by self-report). Variables included age, gender, number of falls within the last 6 months, urinary incontinence, nutrition status and mental health (Kessler psychological distress K10 Scale) <sup>23</sup>. Cognition was assessed using the Abbreviated Mental Test Score (AMTS) <sup>24</sup>.

A battery of physical assessments was used to assess underlying physical functioning. Mobility was assessed using the Timed Up & Go <sup>25</sup>. Balance was assessed using the step test and the Romberg Balance assessment <sup>26</sup>, testing balance for up to 30 seconds with eyes shut. Walking aid used for indoor mobility was also recorded. The 9-Hole Peg Test was used to measure upper limb function <sup>27</sup>. The Frenchay Activities Index is

a self-report functional participation scale and was used to assess participation in a

combination of activities of daily living, leisure (social and participative) and work to

measure overall function and participation <sup>28</sup>. Body mass index (BMI) was calculated

from weight and height measurements.

**Procedure** 

An Initial home visit was conducted by an occupational therapist and physiotherapist for

each potential participant. Descriptive data was collected on demographic and social

information (including sex, age, type of housing, availability of carer) and baseline

measures were also collected at this visit. Participants who met the inclusion and

exclusion criteria were asked to participate in the study and informed consent was

obtained.

Subjects were allocated to domiciliary or centre-based services by a computer

generated list of random numbers. The randomisation sequence was placed into

sealed, opaque numbered envelopes by administration staff not connected with

research. Following consent, the assessing therapist contacted administration staff who

opened the next envelope in the sequence and informed the therapist of subject's group

allocation.

Following allocation, participants were enrolled in the centre-based or home program

starting the following week. The centre-based program was a rolling entry so

participants could enter and exit at any week. After eight weeks of intervention,

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participants were given a home program of three exercises by a physiotherapist as a maintenance measure. All outcome measurements were then collected in the participant's home by an assessor blinded to group allocation. Participants were followed up by monthly telephone contact for falls data and reassessed six months after initial randomisation again by a blinded assessor.

## Statistical analysis

All data were analysed according to initial group allocation on an intention to treat basis. For the analysis of falls, total falls were compared between groups using negative binomial regression with robust 95% confidence intervals adjusted for the time the participant remained in the trial. Negative binomial regression is recommended for analysis of falls data as it often follows an over-dispersed Poisson distribution <sup>29</sup>. This allowed assessment of between group differences while allowing for drop-outs and missing data. In addition, the difference in the proportion of fallers between groups was compared using logistic regression.

Health related quality of life was compared between groups using a generalised estimating equation (GEE) with an exchangeable working correlation structure and robust variance estimates. The GEE is similar to repeated measures ANOVA/ANCOVA. The design of the study is longitudinal with repeated measurements which are correlated with one another in an individual. The GEE is a flexible way of analysing this type of design and can be adapted for a range of data distributions for the dependent variable and produces relatively precise and unbiased estimates even in presence of

missing data (missing at random, missing completely at random or missing not at

random) without need for data imputation 30 31.

Group (centre versus home), assessment point and group-by-assessment point

interaction terms were entered as independent variables. A positive effect of one of the

intervention approaches at one or more of the assessment time-points was revealed by

one or more significant group-by-assessment interaction terms.

Secondary outcome measures were also analysed with a GEE with Gaussian

distribution. Where there was evidence of skewness, gamma distribution was

investigated however results did not diverge considerably from those based on the

Gaussian distribution, hence the gamma distribution results are reported. Analyses

were performed with STATA version IC 9.2. (STATA Corporation, Texas USA).

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Results

**Sample Characteristics** 

Recruitment of the 107 participants took place between June 2004 and June 2008 with

follow ups completed by January 2009. The flow of participants through the trial and the

reasons for drop outs are presented in Figure one. Seventy-six participants completed

all the follow up points (8 weeks and 6 months post recruitment.) The loss to follow-up

was marginally higher for the centre based group (18 participants) than the home based

service (14 participants). Drop outs were minimised as follow ups were conducted in the

patient's home by a visiting therapist. Despite this, there was still a reasonable loss to

follow up (20% at 8 weeks and 29% at 6 months).

Comparisons of baseline characteristics between group are presented (Table one).

Groups were similar at baseline for demographic characteristics and the primary

outcome measures. There was a significant difference in the secondary outcomes of

step test and Frenchay Activities Index (Table two) with the domiciliary cohort

performing poorer on these two measures. As baseline measurements were already

included in the generalised estimating equations, no further strategies were employed to

adjust for this imbalance.

Clinical Outcomes

**Primary Outcomes** 

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The centre based service demonstrated a significant improvement in overall falls rates compared to the domiciliary service. The rate of falls was 1.1 falls per patient year in the centre based program as compared to 2.3 falls per patient year in the domiciliary program. Negative binomial regression analysis with adjustment for time followed up, identified that the incident rate ratio of falls in the centre-based group compared to the domiciliary group was 0.46 (0.22,0.96), p=0.038, indicating that participants allocated to the centre based group service reported approximately half as many falls as participants allocated to the domiciliary service during the 6 month follow-up period. To allow for the difference in drop-out rates between the two programmes, a further analysis was conducted assuming a scenario where every client without full follow up data was assumed to have fallen at the average follow up rate of falls of 1.14 falls per person. This did not change the significance of the results (p=0.046) but altered the incident rate ratio to 0.61 (0.38, 0.99). The proportion of fallers for the six months pre program was n=49 (89%) for domiciliary and n=41 (79%) for the centre based service. For the six months post implementation of the service the proportion of fallers was substantially lower in the centre based cohort 12 (32%) as opposed to 25 (61%) in the domiciliary group (OR 0.31(0.14,0.72), p=0.006). Given the results indicated there could be a slight difference at baseline (although this did not reach significance at p=0.05), the faller at baseline variable was included in the as a co-variate in the logistic regression. This changed the odds ratio point estimate of effect and 95% CI; 0.33 (0.14-0.75) p=0.009; however, the difference between the groups was still significant. The result indicates that the group service is significantly better at reducing the proportion of fallers as well as the total number of falls over the home based service.

Quality of life as measured by the EQ-5D is reported in Table two. Results were not significantly different between groups, although the group program did score slightly higher than the domiciliary program at both eight weeks and six months.

Secondary outcomes are also presented in Table two. Outcomes were not significantly different between the groups with the exception of the centre-based intervention performing better on the upper limb dexterity test. Both groups improved on the baseline physical measures for the timed up and go, step test and reaction time tests. The measure of activity (the Frenchay Activities Index) also improved in both programs approximately equally. Carer strain was recorded initially at low to moderate levels according to the carer strain index <sup>32</sup>. There was a slight reduction in both groups at the 8 week mark immediately following the program, but levels had returned to initial levels by 6 months in both programs.

## **Discussion**

These results support previous research which show the efficacy of multiple component programs which are targeted at high risk and multiple fallers. In addition the results are unique in demonstrating that a centre-based program can be superior in preventing falls to a similar service provided in the home.

Previous studies have established a Minimum Clinically Important Difference threshold of 0.074 for the EQ-5D instrument utility component <sup>33</sup>. The centre-based group reported an improvement in their EQ-5D scores well in excess of this threshold over the 6 month follow-up period, as did participants in the domiciliary group. A difference of 0.12 was modelled in favour of the centre-based group when contrasting the relative amount of improvement between these groups over this time period. However, this difference was not statistically significant providing argument for a larger replication study to be conducted.

This study is in concordance with most studies as it required a self-reported method of falls recording. This method is limited as it is unlikely that all falls will be recalled even if different time-frames and methods (e.g. diary) are used. The use of monthly reported as opposed to daily diary recording could mean that falls rates were underreported by up to 20% <sup>34</sup>, however this should be consistent across groups and thus not effect the between group comparison. There is available health technology such as falls monitoring devices, which while also subject to reliability problems now <sup>35 36</sup>; with further Rehabilitation of fallers: home versus centre

technology improvements may give the ability to more accurately record the rates and causes of falls particularly where clients with cognitive decline are included in the study design.

The loss to follow up of participants within this trail was of concern and could potentially bias the results in favour of the group program. Previously published guidelines on conducting research with frail older persons have noted other trials have similar problems with high dropout rates hampering clinical trials <sup>37</sup>. In addition, the trial was a pragmatic research design with clinicians responsible for the recruitment and treatment phases. Potentially the use of clinical staff contributed to the loss to follow-up in this study with a lack of understanding of the importance of pursuing follow-up assessments for clients who had been non-compliant with treatment protocols. However, the use of a pragmatic design such as this allows the demonstration of the model in real clinical situations and is therefore directly transferable to clinical practice <sup>38</sup>. More participants in the group cohort were lost to follow up for refusal to participate further (13 of 16) than in the home setting (3 participants). It may be possible that factors such as the effort involved in travelling to a centre play a role in whether older people are willing to attend and travel to a centre-based setting. A British survey of over 5,000 older people attitudes to preventing falls found that 36.4% were definitely willing to do strength and balance training programs at home to prevent future falls, whereas only 22.6% would definitely attend a group <sup>39</sup>. It may also be possible that the participants who dropped out represented a sicker cohort than the overall population. Analyses of the subset of drop-outs gives a mean for the EQ-5D of 0.53 (0.32) which is lower but not significantly

different to the sample mean of participants remaining in the study of 0.57 (0.30) by two sample t-test (p=0.55). The Frenchay Activities Index showed a trend to reduced participation at baseline in the group that dropped out; 17.9 (8.5) versus 20.1 (8.9) p=0.23 and timed up and go was slower 24.0 (21.8) versus 19.1 (9.2) p=0.10. As the results were not significant it is not expected that this would influence the overall results of the study. Imputation of missing falls information from the clients who dropped out resulted in a smaller effect size for the group program over the home program; however the overall result was still significant.

Secondary measures did not reflect the differences found in falls rates between the groups. Timed up and go, reaction time and step test have been found to be predictors of risk of future falls <sup>25 40 41</sup> and while these measures improved in the group program over the time period they also improved somewhat equally in the home program. As the study was not powered to detect differences in these secondary measures, a larger cohort or a longer follow up period may be needed to detect differences in these measures. There may also be other factors involved in attending a group over a home program which improve falls risk such as reducing fear of falling which was not measured in this study.

Hence although the group program performed better on the primary outcome measures, it is not appropriate for all community dwelling clients. Indeed, the cohort recruited often have difficulty mobilising and have transportation issues so domiciliary programs are often the only method of delivering a program to these people. Many potential subjects

declined to participate in the trial as they preferred to have a program delivered at home.

## **Implications**

The results indicate that for superior efficacy, where possible, participants should be enrolled in centre-based falls prevention programs; however participants need to be physically able to complete the program and have available transportation. Many people living in the community are not able to access centre-based services and from previous research, both domiciliary and centre based programs have a positive effect for this cohort. Given this, it is important that any service planning to undertake a community program consider providing a combined service delivery model to ensure equity in access for clients who may be unable to attend a centre based service. In addition, subsidised transport should be considered as an option to enable older adults to attend centre-based rehabilitation services.

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SB and TH participated in the study concept and design, analysis and interpretation of

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Table 1: Baseline characteristics of the sample

	Domiciliary	Centre	<i>P</i> -Value	
Measurement	n = 55	n = 52		
Body structure and function				
Age, mean (sd)	$78.7 \pm 8.0$	$79.2 \pm 7.4$	0.65	
Female, n (%)	37 (67)	34 (65)	0.84	
Number of health conditions, mean (sd)	$3.8 \pm 2.9$	$4.2 \pm 2.5$	0.30	
Number of medications, mean (sd)	$6.3 \pm 4.4$	$6.7 \pm 3.9$	0.42	
Urinary incontinence, n (%)	27 (49)	29 (55)	0.72	
Body mass index, mean (sd)	$25.8 \pm 6.2$	$27.7 \pm 6.2$	0.92	
Activity				
Uses walking aid, n (%)	33 (60)	24 (46)	0.12	
Falls, median (IQR)	2 (1,4)	2 (1,3)	0.46	
Falls, mean (sd)	2.3 ± 1.8	$2.15 \pm 2.0$	0.59	
Fallers, n (%)	49 (89)	41 (79)	0.15	
Participation				
Currently driving, n (%)	9 (16)	15 (28)	0.15	
Personal factors				
Drinks alcohol, n (%)	20 (37)	18 (35)	0.85	
Global factors				
Quality of life, mean (sd)	$0.55 \pm 0.32$	$0.57 \pm 0.30$	0.90	

<sup>\*</sup>Falls compared using Mann-Whitney test and GEE, continuous variables compared using t tests and proportions compared using Pearson's chi². Mann-Whitney used to compare total medications and co morbidities.

Table 2: Summary of secondary outcomes and statistical comparisons between domiciliary and centre groups

Construct De	Descriptor	Measurement Name	Initial assessment		Eight week follow up			Six month follow up			
			Domiciliary m(sd)	Centre m(sd)	GEE coefficient (95% CI), p value	Domiciliary	Centre	GEE	Domiciliary	Centre	GEE
and Function Po Mu Po Me Fui Co Me Fui	Muscle Power	Quads Strength(kg)	14.8(6.8)	13.5(4.5)	-1.45 (-3.80,0.90) p=0.23	14.5(6.3)	13.3(4.5)	0.39 (-1.78,2.56) p=0.73	14.3(5.9)	14.2(4.9)	1.01 (-1.21,3.23) p=0.37
	Muscle Power	Lateral Pinch Test(kg)	5.4(2.3)	5.8(1.7)	0.14 (-0.66,0.93) p=0.74	5.7(2.0)	5.6(1.5)	0.15 (-0.29,0.60) p=0.50	5.6(2.0)	5.6(1.5)	0.06 (-0.50,0.52) p=0.98
	Mental Functions - Cognition	AMTS <sup>24</sup>	8.7(1.1)	8.6(1.3)	09 (-0.55,0.36) p=0.68	8.7(1.4)	8.6(1.2)	0.05 (-0.37,0.46) p=0.83	8.9(1.2)	8.7(1.3)	05 (-0.58,0.49) p=0.87
	Mental Functions - Depression	K10 Scale <sup>23</sup>	16.4(6.4)	17.1(5.8)	0.88 (-1.51,3.27) p=0.47	15.6(5.2)	16.7(4.2)	0.81 (-1.52,3.15) p=0.50	14.5(4.1)	16.4(5.8)	1.7 (-0.96,4.35) p=0.21
Activity	Mobility	Timed Up and Go <sup>42</sup>	22.1(12.1)	19.0(16.1)	-3.05 (-8.46,2.35) p=0.27	18.7(8.5)	16.6(12.7)	1.08 (-3.97,6.14) p=0.67	18.5(9.7)	14.5(5.4)	44 (-4.88,3.99) p=0.84
	Balance	Step Test <sup>26 43</sup>	5.4(4)	7.7(3.7)	2.25 (0.79,3.70) <b>p=0.002</b> *	6.6(4.7)	8.8(4.1)	-0.08 (-1.37,1.21) p=0.90	7.0(4.4)	9.6(3.9)	0.17 (-1.45,1.80) p=0.84
	Reaction speed	Simple Reaction Time Test(ms)	379(174)	356(135)	-23.2 (-86.5,40.02) p=0.47	350(225)	335(107)	4.6 (-75.99, 85.20) p=0.91	337(101)	313(89)	-11.63 (-66.80, 43.55) p=0.68
	Upper limb dexterity	9 Hole Peg Test(secs) <sup>27</sup>	31.7(9.9)	30.4(12.2)	-1.32 (-5.57,2.91) p=0.54	31.8(11.2)	27.7(5.6)	-2.02 (-4.69,0.65) p=0.14	31.2(10.2)	26.4(4.5)	-3.16 (-6.27,06) <b>p=0.046</b> †
Participation	Global	Frenchay <sup>28</sup>	17.5(9.1)	21.5(8.0)	3.99 (0.75,7.23) <b>p=0.02</b> *	21.1(9.0)	24.4(6.3)	-1.15 (-3.99,1.70) p=0.43	21.4(9.8)	25.3(6.9)	-0.31 (-3.64,3.03) p=0.86
Environmental Factors	Support and Relationship	Caregiver Strain <sup>32</sup>	5.0(2.2)	3.8(3.1)	-1.17 (-3.16,0.82) p=0.25	4.1(3.8)	3.4(4.2)	0.69 (-2.13,3.52) p=0.63	5.5(4.4)	3.6(2.8)	-0.67(-2.94,1.59) p=0.56
Personal Factors	Lifestyle	Nutrition Score <sup>22</sup>	6.8(3.5)	7.0(2.9)	0.12 (-1.12,1.37) p=0.85	6.6(3.2)	6.5(3.4)	05 (-1.33,1.24) p=0.95	5.6(3.5)	5.9(3.3)	0.32 (-1.30,1.94) p=0.70
Global	Quality of Life	Euroqol VAS	62.4(15.2)	61.1(16.1)	-1.33 (-7.37,4.71) p=0.67	66.3(13.5)	64.5(17.7)	41 (-7.48,6.67) p=0.91	63.5(19.7)	68.5(18.2)	6.2 (-3.56,15.99) p=0.21
	Quality of Life	EQ-5D	0.55(0.32)	0.57(0.30)	0.01 (-0.11, 0.13)	0.6 (0.25)	0.67 (0.25)	0.02 (-0.12, 0.17),	0.63 (0.31)	0.78 (0.18)	0.12 (-0.03,0.28),
	LIIE				p=0.90			p=0.75			p=0.11

<sup>\*</sup>significant difference at baseline †significant difference at follow up assessment

Figure 1: Flow of participants through the study

