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PROTOCOL

Improving quality of life by increasing outings after stroke: Study protocol for the *Out-and-About* trial

Annie McCluskey[1], Louise Ada[2], Sandy Middleton[3], Patrick J. Kelly[4], Stephen Goodall[5], Jeremy M. Grimshaw[6], Pip Logan[7,] Mark Longworth[8], and Aspasia Karageorge[1]

[1] Department of Occupational therapy, Faculty of Health Sciences, The University of Sydney, NSW, Australia
[2] Department of Physiotherapy, Faculty of Health Sciences, The University of Sydney, NSW, Australia
[3] National Centre for Clinical Outcomes Research, Nursing & Midwifery, Australian Catholic University, NSW, Australia
[4] Sydney School of Public Health, The University of Sydney, NSW, Australia
[5] Centre for Health Economics Research and Evaluation, University of Technology Sydney, NSW, Australia
[6] Clinical Epidemiology Program, Ottawa Health Research Institute and Department of Medicine, University of Ottawa, Ottawa, Canada.
[7] University of Nottingham, England, UK
[8] NSW Agency for Clinical Innovation, NSW, Australia

Almost one third of Australians need help to travel outdoors after a stroke. Ambulation training and escorted outings are recommended as best practice in Australian clinical guidelines for stroke. Yet fewer than 20% of people with stroke receive enough of these sessions in their local community to change outcomes. The Out-And-About trial aims to determine the efficacy and cost-effectiveness of an implementation program to change team behaviour and increase outings by people with stroke. A two-group cluster-randomised trial will be conducted using concealed allocation, blinded assessors and intention-to-treat analysis. Twenty community teams and their stroke clients (n=300) will be recruited. Teams will be randomized to receive either the Out-And-About program or written guidelines only. The primary outcome is the proportion of people with stroke receiving multiple escorted outings during therapy sessions, measured at baseline and 13 months post-intervention. Secondary outcomes include number of outings and distance travelled, measured using a self report diary at baseline and six months post-baseline, and a global positioning system (GPS) after six months. Cost-effectiveness will measure quality-adjusted life years and health service use, measured at baseline and six months post-baseline. A potential outcome of this study will be evidence for a costed, transferable implementation program. If successful, the program will have international relevance and transferability. Another potential outcome will be validation of a novel and objective method of measuring outdoor travel (GPS) to supplement self-report methods. This trial is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12611000554965)

KEY WORDS: *Physical therapy; physiotherapy; occupational therapy; rehabilitation; knowledge translation; walking*

BACKGROUND

After a stroke, almost one third of Australians need help to walk or travel outdoors (1). Although treadmill training and practice of mobility skills in the hospital gym can help people with stroke to walk faster and further (2), gains made indoors do not automatically translate into improved performance outdoors. Ramps, escalators and crowded shopping malls continue to challenge mobility. People with stroke report a persistent loss of confidence to the extent that many will not go out alone (3). This loss of confidence decreases physical activity levels and quality of life.

Multiple escorted outings and travel training with a therapist during rehabilitation enable people with stroke to get out more often (4). This intervention is now recommended as best practice in Australian national stroke guidelines (5). Despite this evidence, most people with stroke do not receive escorted outings or outdoor training (6). Improved indoor walking does not automatically lead to improved outdoor walking or transfer to other day-to-day outdoor activities. Even after weeks of indoor physiotherapy, people with stroke report persistent loss of confidence in community mobility (3) resulting in few community outings and increased social isolation.

Implementation programs use a number of interventions to change practice (7, 8) including dissemination of clinical guidelines and educational materials (9), educational meetings, feedback from audits (10), reminder systems and a multifaceted program of interventions. Our earlier pilot study evaluated an implementation program to promote escorted outings and outdoor training (6) we demonstrated that it was safe and feasible for community teams to provide multiple outings sessions to people with stroke without additional resources or adverse patient outcomes. After participating in the half-day training program, one team was able to provide multiple escorted outings to 67% of their clients with stroke (6). As a result, more people with stroke went outdoors alone when they wanted.

Previous studies involving people with stroke have measured outings using self-report methods (4, 6). While diaries and calendars help recall, more reliable methods are needed. As well as a self-report diary, this study will use a novel method, a global positioning system (GPS), to track how far a person travels and the number and frequency of outings. GPS has been used in dementia research to track people who wander (11, 12) but has had limited use in rehabilitation research.

In summary, this study aims to determine the efficacy and cost-effectiveness of an implementation program to change community team behaviour and increase outings by people with stroke. The research questions are:

1. Do experimental community teams that receive the *Out-and-About* program deliver more escorted outings to people with stroke than control teams which receive written clinical guidelines only?
2. Do people with stroke that are seen by experimental teams: (a) travel outdoors more often and travel further; (b) report better quality of life and physical well being, and (c) use fewer health services than people with stroke seen by control teams?
3. Is the *Out-and-About* program cost-effective?

METHODS

Design

A two-group, cluster-randomised trial will be conducted, using concealed allocation and intention-to-treat analysis. Community teams will be randomised to receive the *Out-and-About* program or

written clinical guidelines only. After teams have been recruited and randomised, people with stroke from each team will be sequentially recruited. Community team outcomes will be measured before randomisation and 13 months later by a blinded assessor. Outcomes for people with stroke will be measured at baseline (upon recruitment) and six months later by a blinded assessor (see study flow in Figure 1). To ensure team members remain blinded, only team (cluster) guardians will be privy to study aims. The trial has been registered with the Australian and New Zealand Clinical Trials Registry (ACTRN 126110000554965).

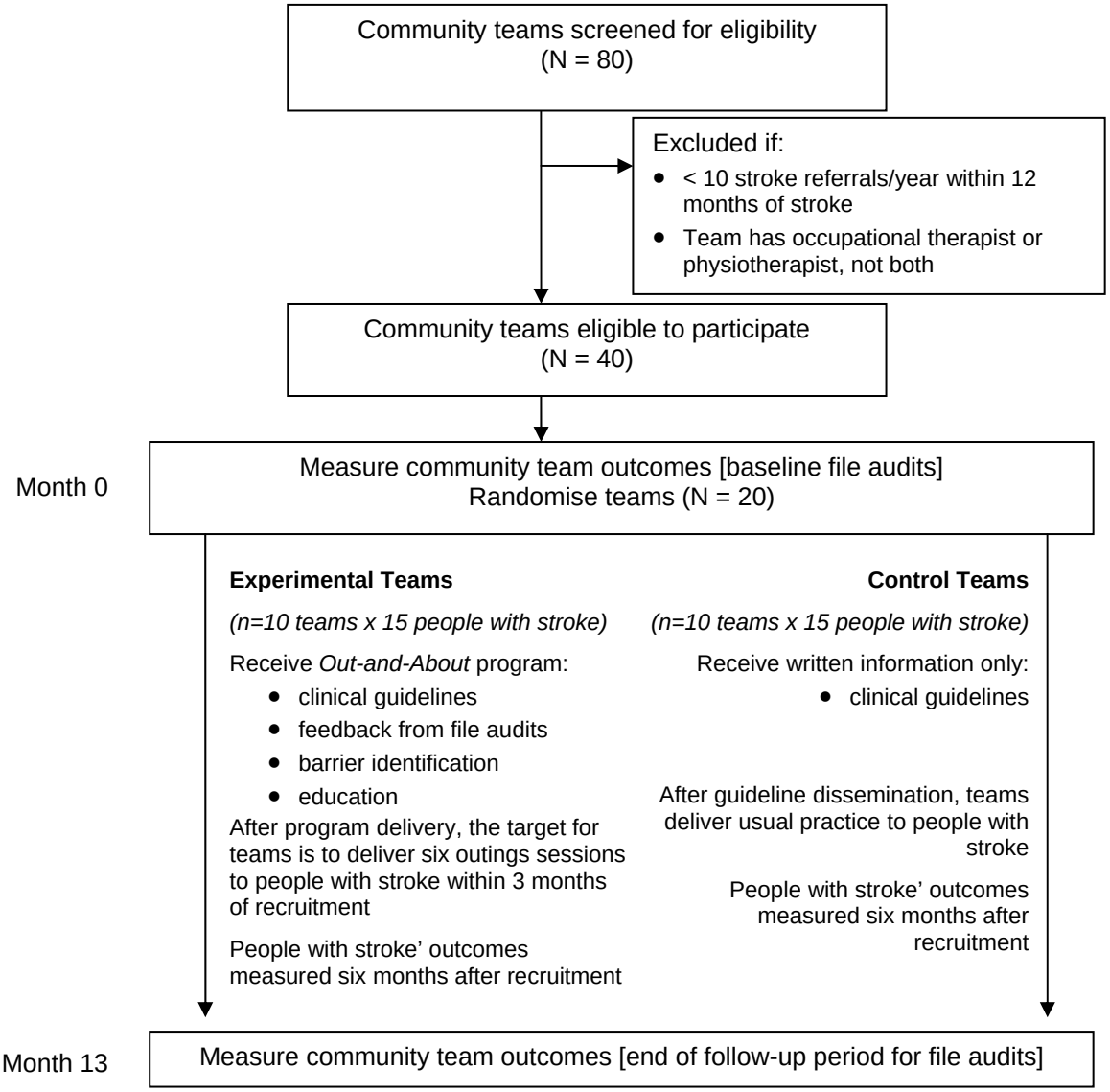

Figure 1. Design of the study

Participants *(community teams and people with stroke)*

Community teams will be recruited across Sydney, the Illawarra and central coast regions of New South Wales, Australia. A list of non-inpatient stroke services generated from NSW Health, private hospitals, aged care service and allied

health private practice directories was created in 2009. A researcher will contact each of the teams on the list to discuss eligibility and, where suitable, invite teams to participate. The inclusion criteria for community teams are: at least one occupational therapist and one physiotherapist are employed on the team (a typical configuration in Australia); the team receives referrals for at least 10 people with stroke per year (date of stroke within 12 months of the person commencing therapy); the cluster guardian or team leader consents to participation in the trial.

People with stroke referred to these community teams will be informed by a physiotherapist or occupational therapist on the team that participants are being sought for a study taking place across multiple sites. If a person with stroke consents to hearing more about the study, the therapist will provide contact details to the research team. The person with stroke will then be contacted by an independent recruiter, blind to group allocation, and invited to participate. The inclusion criteria for people with stroke are: over 18 years old and sustained a stroke in the previous 12 months; able to read and understand spoken English to a level where they can understand the participant information sheet, complete the consent form and carry out self-report outcome measures with/ without an interpreter or next-of-kin; living at home, in a hostel or nursing home; able to walk 10 metres outdoors with/ without a walking aid or supervision; not currently getting out of the house as often or as far as desired, or without undue assistance, measured subjectively through response to two questions *"Are you currently getting out of the house and into the community as often as you would like?"* and *"Are you happy with the way you are getting around? For example, are you relying on other people?*. In addition to demographic information, distance walked in six minutes will be collected at baseline, to describe the walking ability of participants. The 6 Minute Walk Test (13, 14) will used for this purpose.

Randomisation *(community teams only)*

Randomisation will be conducted at the team level to reduce contamination (15). The NHMRC Clinical Trials Centre at the University of Sydney will conduct off-site concealed allocation of teams to either the experimental or control intervention, using random computer-generated numbers. Minimisation will be used during randomisation to ensure balance on the following factors: primary mode of service delivery (hospital-based or home-based appointments), type of health service (public or private), caseload size in the previous 12 months (high or low), and average number of outings conducted at baseline (high or low).

Intervention *(community teams and people with stroke)*

Experimental community teams will receive the *Out-and-About* program and be asked to deliver six escorted outings per person with stroke during rehabilitation. The program is conducted at the team worksite as a single 2-hour, face-to-face workshop. The program is conducted by the lead investigator and attended by all physiotherapists, occupational therapists and therapy assistants employed on the team (6). The lead investigator will present three program components: written guideline recommendations, education, and feedback from patient medical record ('file') audits. These components include:

Written guideline recommendations (5): A printed copy of the National Stroke Foundation's 'Clinical guidelines for stroke management 2010' will be provided to each team leader at the workshop. The original trial intervention (4, 6, 16) and guideline recommendation will be discussed at the workshop.

Education: Printed training materials and education will be provided at the 2-hour workshop about the evidence-based escorted outing intervention. This education is designed to address known and local barriers to delivering the intervention to people with stroke (17). Training materials include: (a) a screening checklist of questions to ask people with stroke about outings, modes of travel and driving status; (b) evidence-informed protocols (4, 6, 16) or upgrading walking distance and difficulty, bus and train travel and road safety, developed by two of the investigators; (c) local community transport information, and (d) a printed form to help teams record escorted outings.

Feedback from file audits about current practice: Medical records from a consecutive sample of the 15 most-recently discharged stroke patients from each participating team will be audited by the research team. Feedback will address the number of people with stroke receiving escorted outings and other outdoor-related therapy, the number of sessions per person, stroke severity and latency per team. The target discussed with experimental teams, but not control teams, will be for people with stroke seen sequentially to receive six escorted outings during their rehabilitation program. These sessions will be conducted in local streets and suburbs and may include public transport travel, practice negotiating shopping malls, help to return to driving and supervised practice using mobility equipment such as a motorised scooter where relevant. Escorted outings will be delivered by a physiotherapist, an occupational therapist, and/or a therapy assistant if one is available. The configuration of sessions and session content will be individually tailored.

Control community teams will be sent a printed copy of the National Stroke Foundation's *'Clinical guidelines for stroke management 2010'* by post (5).

Measurement *(community teams, people with stroke and cost)*

Data will be collected at baseline and 13 months post-intervention (1 month bedding-down period + 12 months). A 'bedding down' period will be included to allow teams time to incorporate knowledge gained during training into practice. To ensure balance, a one-month bedding-down period will also be applied to control teams.

Primary outcome for community teams: The primary outcome is the proportion of people with stroke who have been treated and discharged, and received four or more escorted outings from physiotherapists, occupational therapists or therapy assistants during their therapy program. These data will be collected by medical record audit from the files of new people with stroke seen over the 12 months post-intervention period, excluding the one month bedding-down period. File auditors will be blinded to study aims and group allocation. This outcome addresses the first research question by measuring changes in team behaviour.

Secondary outcomes for community teams: A blinded assessor will measure the *number of escorted outing sessions* delivered by physiotherapists, occupational therapists and therapy assistants. During the file audits, these data will be extracted using agreed definitions.

Secondary outcomes for people with stroke will be measured at baseline and six months post-recruitment, with data collected and analysed by a blinded assessor who is unaware of group allocation. Number and nature of outings will be recorded prospectively for seven consecutive days (these outings do not involve therapists). A self-report paper diary will be used for this purpose. Outings will be recorded by the person with stroke, and returned by mail to the

research team.

Distance travelled during outings will be measured using a personal global positioning system (GPS) tracking device, at the six month time-point only. A number of these devices have been purchased by the research team from an Australian company Ezy2c Online GPS Monitoring (device EZ 23 Personal Tracker, www.Ezy2C.com.au, see Figure 2a). People with stroke will be shown how to operate and recharge the device by a research assistant. They will be asked to wear or carry the device during waking hours for the next seven consecutive days. A GPS device has been used in studies involving healthy adults (18) and people with dementia who wander (11) and was found to be a feasible and reliable way of collecting data in our pilot study involving 20 community-dwelling people with stroke (personal communication, A. McCluskey). Data on distance travelled over seven days will be downloaded for analysis into an Excel spreadsheet.

Secondary outcomes which address cost-effectiveness and the third research question will be calculated using a stepped economic evaluation. The costs of providing the *Out-and-About* program will be determined by calculating program costs, (training plus the cost of delivering the outings sessions) and any cost-offsets due to reduced health service use. Outcomes to be reported will include improvements in quality of life (QoL). The incremental cost-effectiveness ratio will be calculated relative to the control group (cost per QALY).

- *Quality of life (QOL*): The health benefits associated with providing the *Out-and-About* program will be estimated using the Short Form 36 Health Survey (SF-36)(19), the most widely used measure of general health (available at http://www.SF-36.org). For the economic evaluation a preference-based single utility measure, using Australian preference weights, will be derived from these data using the SF-6D as described by Ara and Brazier (20). The SF-36 will be administered at baseline and six months post-randomisation. The aim of the QOL analysis will be to describe what aspects of QOL are affected, and to what extent, if any, QOL is improved in the intervention group.
- *Routine health service use:* People with stroke will be asked to consent to the collection of individual patient data. Individual Medicare data will be obtained from the Department of Human Services, showing claims made under the Pharmaceutical Benefits Scheme (PBS) and Medicare Benefits Scheme (MBS) during the study period. The former relates to pharmaceutical usage; the latter relates to medical services such as specialist and general practitioner visits/procedures. Admitted patient data will be obtained from the Demand and Performance Evaluation Branch, NSW Health. The total health service costs will be derived by multiplying the resources used by the relevant MBS item fee, PBS price or Australian-Related Diagnosis Resource Group (AR-DRG).
- *Program costs:* This category will include the cost of workshop training materials, trainer's time and opportunity cost of the trainee's time when attending the workshops.
- *Outing costs:* The number of escorted outings delivered to each person with stroke will be counted during file audits. Cost of outings will be determined based on average session time and travel time.

Sample size

The study has been powered with respect to the primary outcome. In our pilot study (6), 25% of people received four or more escorted outings with a therapist before intervention. Assuming that study participation and guideline dissemination

increases this rate to 30% of people with stroke seen by control teams, the *Out-and-About* program will be considered successful if 50% of people with stroke seen by experimental teams receive four or more outings, that is, a difference of 20%.

Twenty teams (clusters) will be recruited with outcomes collected on an average of 15 people with stroke per team. While the pilot study indicated that the intracluster correlation coefficient (ICC) was close to zero (<0.01), this ICC was estimated using data from a small number of clusters (n=4). With an ICC of zero, we would need to recruit 186 people with stroke to detect a 20% difference with 80% power at a 5% significance level (2 sided). To avoid an underpowered study, we will recruit 300 people with stroke. This sample size will allow us to detect a 20% difference with 80% power, if the ICC is 0.04, and 90% power, if the ICC is 0.01.

Statistical Analysis

Intention to treat analyses will be conducted. At the patient level, analysis will be adjusted for clustering of patients within teams using mixed models. A logistic mixed model will be used to analyse the binary outcome of people with stroke receiving four or more outings. The number of outings (a count outcome) will be analysed using a Poisson mixed model and distance travelled (a continuous outcome) will be analysed using a linear mixed model. All regression models will include treatment group as a covariate and a random effect for teams, to adjust for any clustering effects. Baseline characteristics will be compared between groups; any potential confounding factors found to be imbalanced between groups, such as age and mobility, will be included as covariates in the regression models. Model assumptions will be checked and appropriate adjustments to the analysis will be made where necessary. For example, distance travelled and walking capacity are likely to be skewed, therefore the linear mixed models will be fitted to some transformation of these outcome variables (e.g., logarithm).

The cost-effectiveness component will be presented as net costs and benefits for experimental and control teams. The incremental cost-effectiveness ratio (ICER) will be calculated for teams and people with stroke. The cost-effectiveness of change in team behaviour will be determined by the incremental cost per additional outings session. For people with stroke, the analysis will be extended to include an incremental cost per QALY, based on improvements in utility scores. The incremental QALY will represent the improvement in quality of life between people with stroke seen by experimental and control teams. A within trial time horizon will form the base case analysis. Extrapolations beyond the trial period (e.g. five year time horizon) will be based on various assumptions about the sustainability of the treatment effect. Sensitivity analyses will be undertaken to explore the robustness and validity of cost-effectiveness data and test any assumptions that were used in the economic model.

DISCUSSION AND CONCLUSIONS

For people with stroke, the potential benefits of the *Out-and-About* program include increased physical activity levels and social participation, less isolation and dependence on carers for transport.

For the healthcare system, fewer hospital readmissions may help reduce access block and healthcare costs. Benefits for health departments will be realised if the *Out-and-About* program is cost-effective and changes team behaviour. The program could then be rolled out nationally in collaboration with health services and professional associations.

For rehabilitation professionals, benefits will include making escorted outings part

of routine practice, supported by an evidence-based implementation protocol. No such protocol currently exists. The protocol and training materials could also be tested with other rehabilitation populations such as people with multiple sclerosis or brain injury. Health service researchers will be able to replicate the implementation methods across fields and settings. Rehabilitation researchers will also benefit from new knowledge about the GPS device. This measurement innovation can be used to measure distances travelled by wheelchair or electric scooter users, and to measure the effect of interventions to increase travel. Unlike pedomoters and other wearable monitoring devices (21), a GPS will track distance travelled in a vehicle and topography of outings.

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AUTHORS' CONTRIBUTIONS

AM conceptualized the study. AM, LA, SM, SG, JG and PK contributed to design and the procurement of funding. AM and LA developed procedures for implementing the protocol. All authors contributed to, and have checked the final manuscript.

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CONFLICT OF INTEREST

None declared.

CORRESPONDENCE

Dr Annie McCluskey, Department of Occupational Therapy, Faculty of Health Sciences, Universtiy of Sydney, PO Box 170, Lidcombe NSW 1825, Australia. Email: annie.mccluskey@sydney.edu.au