BMJ Open

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Journal:	*BMJ Open*
Manuscript ID:	bmjopen-2015-008900
Article Type:	Research
Date Submitted by the Author:	26-May-2015
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Primary Subject Heading:	Rehabilitation medicine
Secondary Subject Heading:	Patient-centred medicine, Neurology
Keywords:	Stroke < NEUROLOGY, REHABILITATION MEDICINE, PUBLIC HEALTH

Title: A feasibility study of an integrated stroke self-management programme: a cluster randomised controlled trial

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Cover title: Self-management in stroke rehabilitation

Tables:

Figures:

Key words: Self-management, Stroke, Rehabilitation

ABSTRACT

Objectives: To test the feasibility of conducting a controlled trial into the effectiveness of a self-management programme integrated into stroke rehabilitation.

Design: A feasibility cluster randomised design was utilised with stroke rehabilitation teams as units of randomisation.

Setting: Community based stroke rehabilitation teams in London.

Participants: 78 patients with a diagnosis of stroke requiring community based rehabilitation

Intervention: The intervention consisted of an individualised approach to self-management based on self-efficacy principles. Clinicians were trained to integrate defined self-management strategies into scheduled rehabilitation sessions, supported by a co-produced patient-held workbook.

Main Outcomes measures: Patient measures of quality of life, mood, self-efficacy and functional capacity and health and social care utilisation were carried out by blinded assessors at baseline, six weeks and three months. Fidelity and acceptability of the delivery was evaluated by observation and interviews.

Results: Four community stroke rehabilitation teams were recruited, and received a total of 317 stroke referrals over 14 months. Of these 138 met trial eligibility criteria and 78 participants were recruited (24.6%). Demographic and baseline outcome measures were similar between intervention and control arms, with the exception of age. All outcomes measures were feasible to use and clinical data at 12 weeks was completed for 66/78 participants (85%; 95%CI 75% to 92%). There was no significant difference in outcomes between the arms of the trial (95%CI, p=0.22). But measures of functional capacity and self-efficacy showed responsiveness to the intervention . Observation and interview data

confirmed acceptibility and fidelity of delivery according to pre-detrmined criteria Costs varied by site.

Conclusions: It was feasible to integrate a stroke self-management programme into community rehabilitation using pre-determined criteria. Minimal data was lost to follow up. The trial design supports testing clinical and cost effectiveness of integrated self-management in a definitive trial.

Clinical Trial Registration-URL: http://www.controlled –trials.com. Unique identifier: ISRCTN42534180

Strengths and Limitations

- This is the first feasibility trial of an integrated approach to stroke self-management, study recruitment and findings support testing the intervention in a definitive trial
- Community stroke rehabilitation teams had a high turnover of staff and training needs were higher than anticipated but intervention fidelity was maintained
- The intervention requires some modification to be more accessible for those patients with cognitive and communication impairments and those having less than six sessions with rehabilitation clinicians.

INTRODUCTION

Significant improvements have been made in the quality and effectiveness of acute stroke care across the developed world.[1-3] But variation in the availability of post hospital rehabilitation and support for self-managed activities still exists,[3-4] and the prevalence of mood disorders and social isolation post stroke remains high.[5-7] As the overall global burden of stroke increases,[1] expenditure on the direct and indirect costs of stroke care is likely to rise, and in the United Kingdom (UK) this currently constitutes 5% of the total National Health Service (NHS) budget (£8 billion).[8] Stroke and associated care models are still largely defined by acute medical ideologies and there is an inequity in attention to address long term psychological and social sequelae.[9-11] Arguably unmet needs post stroke could be exacerbated by care models which foster dependency on professional expertise in the acute stages combined with a paucity of programmes to facilitate coping and self-management in the longer term.

One alternative to existing care models is the use of self-management programmes (SMPs) which build on growing level 1 evidence from other long-term conditions.[12-14] SMPs can be 'provider-based' delivered by healthcare professionals integrated into usual care or 'patient-based' when supplied in addition to care through group or individual education.[16-18] Broadly self-management focuses on those actions individuals and others take to mitigate the effects of a long term condition and to maintain the best possible quality of life.[12-14] The variation in programmes makes it difficult to compare outcomes, but effective SMPs can improve mental wellbeing, quality of life and reduce hospital readmission rates.[12-16]

The UK National Stroke Strategy in 2007 advocated self-management initiatives to address long term unmet needs,[17] and national guidance recommends that all patients be offered training in self-management skills.[18] Research to develop and evaluate stroke SMPs mainly

comprises feasibility and phase II trials of group based programmes, which, whilst demonstrating some impact on function, mood and quality of life,[9, 19, 20] will not be accessible for certain patients with communication and cognitive impairments.[21] We hypothesised that an individualised stroke self-management intervention which can be integrated into existing rehabilitation may extend the reach to more patients.[11, 19]

Following the Medical Research Council Framework for the Development and Evaluation of Complex Interventions [23] several studies have been conducted to inform the development of an individualised SMP.[22, 24] The Bridges Stroke SMP is based on social cognition theory [25,26] and incorporates a patient held workbook used by rehabilitation professionals to support self-management skills. Studies have demonstrated preliminary proof of concept and feasibility when provided in addition to rehabilitation.[22, 24.] However a SMP delivered in addition to routine stroke rehabilitation has cost and time implications, especially when utilising an individualised approach. If the same programme could be integrated into existing rehabilitation this may offer a solution which could be both clinically and cost-effective.

The aim of the study was to test the feasibility of conducting a cluster randomised controlled trial into the effectiveness of a stroke SMP (Bridges) integrated into community rehabilitation. We aimed to evaluate key trial parameters such as recruitment and retention of participants, randomisation, utility and sensitivity of outcome measures, levels of missing data, and preliminary indications of effectiveness to inform calculation of a sample size for powering a full trial. An estimation of resources required to deliver the intervention and indications of likely cost effectiveness were also investigated. Fidelity of the intervention delivery, training required and acceptability of the intervention to patients and clinicians was evaluated.

METHODS

Design

A feasibility cluster randomised design with a nested process evaluation was utilised with community stroke rehabilitation (CSR) teams as units of randomisation. Sites were eligible if they comprised multiprofessional teams with stroke specialist skills delivering post hospital rehabilitation according to quality criteria set out in UK National Clinical Guidelines for Stroke.[21]

Selection of sites

Twenty–one CSR teams meeting eligibility criteria in the London area were sent information about the study via a group email used for the pan-London Stroke Rehabilitation Network. Four teams were selected that had not taken part in any previous self-management training in the previous 12 months and met all eligibility criteria. Team consent was obtained from the lead clinician acting as a cluster guardian.

Randomisation

Allocation of CSR teams to either an intervention or control cluster was carried out by a local clinical trials unit via web randomisation once teams had been recruited and given consent to participate.

Intervention

Intervention site teams undertook training on theory, research and practical application of the Bridges SMP. Training delivery in intervention sites adhered to a pre-determined protocol based on seven key principles of the SMP; these were developed through previous research and in consultation with key stakeholders (Table 1). [22,24]

Table 1. Seven key principles of the Bridges stroke self-management programme

Key Principle	An example of what might be observed to demonstrate use of key principle
Problem solving Not being given solutions but encouraged to come up with ideas and strategies	Clinician reminds patient about how they have found ways around a problem or challenge before e.g. "I remember when you had to work really hard to do 'x' – how did you manage that, is there any way you can use the same skills now?"
Reflection Attributing changes and progress to personal effort/not skills of therapist	Clinician encourages regular reflection in workbook to capture changes and how progress is being made e.g. Highlighting the value of reflecting on progress: "It will help to have a reminder about all the things you have managed to do, however small"
Goal setting Avoiding therapy-led goals, encouraging small steps for mastery experiences and longer term goals	Patient is encouraged to think of small things they could do towards their goal, instead of being discouraged from an 'unrealistic target' e.g. "What's a small thing you could do this week that might help you towards that?"
Accessing resources Using resources available to achieve personal goals	Clinician uses open style coaching questions e.g. "What support could you use to help you get to that?"

Self-discovery Finding out new ways of doing things and trying out different activities	Clinician asks about the ways the patient managed to do challenging things before their stroke and what strategies that have worked for them previously e.g. Clinician is heard discussing the need to take some risks, and try things out- and the benefit to learning about what is possible
Activity Encouraging any activity however small	Clinician asks what they have managed to do in the last week, what they are most pleased with in terms of their activity and working with patient to plan ways to increase activity e.g. "What have you managed to do in the past week that you are really pleased about?"
Knowledge Knowledge about stroke, but also about self	Clinician explores what the patient knows about their stroke, what they would like to know and any concerns that patient feels might be hampering rehabilitation e.g. "Are there any things that you are worried might be affecting your rehab? Is there one small thing we can work towards that might help?"

The Bridges SMP aimed to be distinct from routine stroke rehabilitation provision in two main ways;

1. One-to-one rehabilitation sessions using seven predetermined strategies integrated into each therapy session to support self-management activities.

2. A stroke workbook which included vignettes, activities, ideas and solutions from other stroke survivors for successful self-management and space to record and reflect on goals and progress.

Recruitment

Consecutive stroke patients referred for CSR were screened by the community rehabilitation teams, then recruited and consented by members of the research team not blinded to allocation. Patients were eligible if they had a confirmed diagnosis of stroke and could follow-a two stage command (either verbal or non-verbal) or read simple text and/or have a carer to assist. Exclusion criteria for communication level and patients requiring less than six sessions was informed by previous research.[22, 24]

Stroke participants allocated to the intervention clusters were introduced to the stroke workbook and the seven self-management strategies by the therapist integrated into existing CSR sessions. Participants in control sites received CSR as usual, which included access to physiotherapy, occupational therapy and speech and language therapy if required.

Sample size

As this was a feasibility study, a prospective sample size calculation was not conducted. We aimed to recruit 80 stroke participants across the four sites over 10 months, which appeared realistic given the teams' referral rates.

Assessments

Data were collected in participants' homes by research assessors blinded to group allocation. Clinical outcomes were collected at baseline (within two weeks from commencing rehabilitation), six weeks and twelve weeks after baseline.

Feasibility, fidelity and acceptability

The feasibility of recruiting and retaining participants was assessed from study records, and characteristics of those who were not eligible, consent and completion rates were analysed. Participants' age, sex, social support, socioeconomic status and past medical history were described and compared between groups to test randomisation.

Fidelity and acceptability of the delivery of the intervention was determined by observing a proportion of rehabilitation sessions using a checklist to record patient and professional activities and behaviours against each principle component of the SMP. The checklist was piloted to enable a method to compare self-management support delivered in intervention and control sites that could be used in a larger trial. Patients and clinicians were interviewed in each site to compare their experiences and understanding of self-management; those in the intervention site were specifically asked about the feasibility and acceptability of using self-management strategies and workbook.

Clinical outcomes

Clinical measures found sensitive to change in previous self-management trials and validated in stroke populations were utilised [9, 20, 24] and included the Stroke and Aphasia Quality of Life (SAQOL) scale,[27] Nottingham Extended Activities of Daily Living Scale (NEADL) of functional ability,[28] Stroke Self-Efficacy Questionnaire (SSEQ)[29, 30] and Hospital Anxiety and Depression Scale (HAD).[31] The Medical Outcomes Trust's Short Form 12 (SF12) was included to provide a generic measure health related quality of life.[32] Ease of data capture and levels of missing data were assessed for each outcome measure.

Although the study was not powered, a statistical analysis was conducted to gain a preliminary indication of effectiveness and of the feasibility of such analysis. The analysis enabled an assessment of the sensitivity of different outcome measures and provided a basis for a sample size calculation for the full trial.

Statistical Analysis

Considering feasibility, we compared levels of missing data between intervention and control sites using Fisher's exact test. In order to adjust for age, a multilevel regression model was fitted to each clinical outcome. This is a common approach to cluster randomised clinical trials, and utilises all data, even if a participant is missing some. Group allocation was purely on the basis of site, forming an intention-to-treat analysis. Inter-participant variability was represented as a random intercept, and age, time and group allocation were included as fixed effects. Group differences were quantified at six and twelve weeks, and a composite null hypothesis that both were equal to zero was assessed by Wald tests. This represents no mean difference between groups in how the outcomes change over time. These analyses were conducted in Stata version 11.2 software (StataCorp, College Station, TX) using command 'xtmixed'.

Sample size calculations for a future trial were calculated using Stata software (command 'sampsi'), assuming standard deviations observed in this study for NEADL and SAQOL, 80% power requirement, and a range of putative minimum clinically important differences: NEADL from 2 to 5 in steps of 0.1, and SAQOL from 0.1 to 0.5 in steps of 0.01.

Economic analysis

To estimate the resources involved in delivering stoke rehabilitation in each site, data were collected at individual patient level from therapist records on the number of CSR sessions, and face-to-face contact time in minutes. Physical resources were converted to costs using validated national unit costs [33] . Costs associated with patient-related non face-to-face time was calculated under three alternative assumptions, Total costs were compared across sites.

The feasibility of capturing health and social care utilisation from participants was assessed using a bespoke self-report questionnaire administered to participants at week 6 and 12. Items included contacts with General Clinician (GP), practice nurse or other professionals, social care and help from family and friends. The purpose was to explore if use of SMP reduced demands on other services, compared to the control group. EQ-5D health state utility weights, using a published transformation[40] of the SF-12 profile measure of quality of life, was to be tested for deriving quality adjusted life year (QALY) gains.

Ethical approval

The London Surrey Borders National Research Ethics Committee gave ethical approval for this study (11/LO/1450) with local Research & Development approval granted from each of the cluster sites.

RESULTS

Intervention fidelity and acceptability

Overall 63 occupational therapists, physiotherapists, speech and language therapists and rehabilitation support workers, received training. This number was higher than expected because of clinician turnover.

The feasibility of monitoring intervention fidelity was evaluated through observations of a consecutive sample of 14 participants (18%, control n=7, intervention n=7). The checklist was feasible to use and identified whether CSR incorporated behaviours and activities relating to core self-management principles. Clinicians in the intervention sites showed use of between five to seven self-management principles, whereas those in the control site showed evidence of using two or less.

A consecutive sample of patients (n=23) were interviewed and focus groups were carried out with all clinicians (n=34) across sites at the end of the trial to explore intervention feasibility and acceptability. Findings showed shared understandings of self-management in patients and clinicians within the intervention clusters, which reflected the underlying principles of the SMP and will be reported more fully elsewhere.

Feasibility

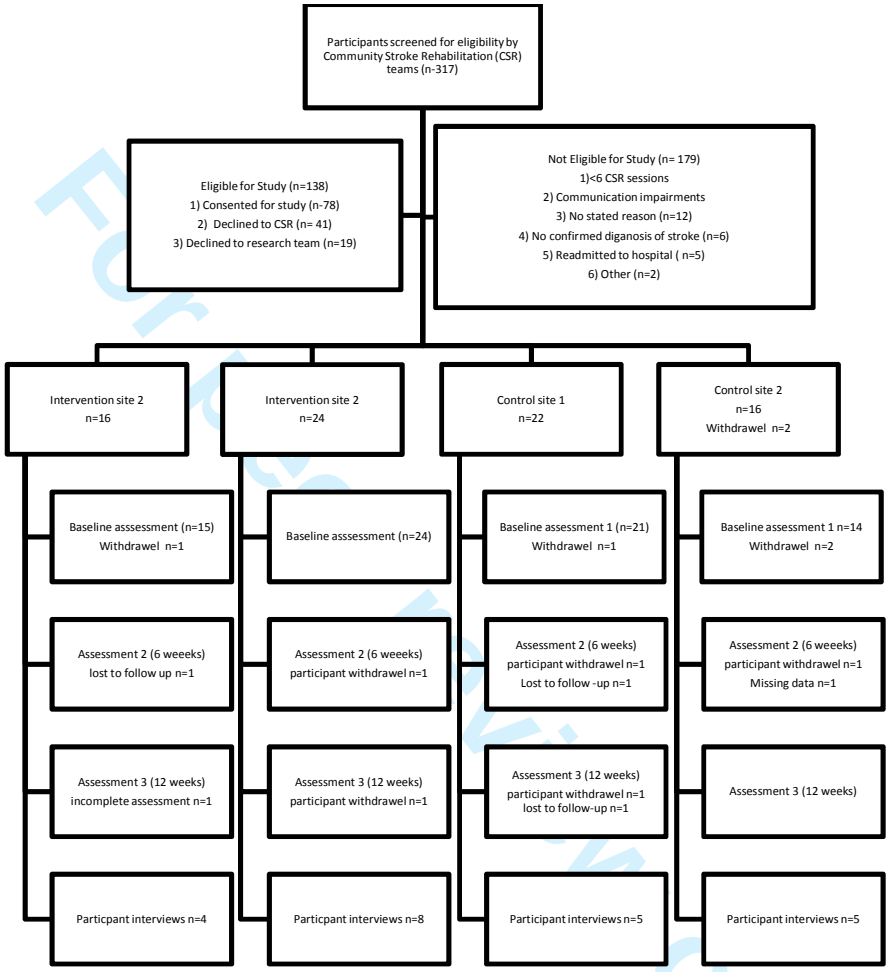
Recruitment rates: Four sites were recruited from six CSR teams in London that expressed an interest and were eligible, exluded sites had either previously taken part in self-management training or were likely to undergo significant re-organisation during the trial period of 22 months.Participant recruitment occurred between July 2012 and August 2013, 138/317 patients were eligible to participate (44%; 95%CI: 38% to 49%) across four sites.).

Recrutment took 14 months which was longer than the anticipated 10 months, this was due to restructuring of some community services and a requirement for further training for new staff. Of those eligible and invited to participate, 78/138 consented (57%; 95%CI: 48% to 65%) and were recruited to the trial (at a rate of 5.57/monthControl sites recruited n=38 compared to n=40 in intervention sites. The main reason for non-eligibility were patients not requiring six rehabilitation sessions or more (58%), followed by patients with cognitive and communication impairments (17%).

Completion rates

The research protocol was successfully delivered and outcome assessors remained blinded to the intervention throughout the duration of the trial. Figure 1 shows rates of completion varied slightly between control and intervention sites. Thirty-nine participants (98%) completed baseline measures and 36 participants completed week 12 outcome measures (90%) in intervention sites, compared to 35 (92%) completing baseline outcomes and 30 (79%) competing week 12 outcomes measures in control sites. Reasons for withdrawal included ill health, change in family circumstances with only three cases of withdrawal due to burden of outcome measurement (nature of the questions (n=1) and the volume of questions (n=2).

Figure 1. Study flow diagram



Randomisation

Participant characteristics

Table 2 shows an even distribution of men and women in intervention sites but more men took part in the control sites. Days post stroke data were missing in 8/78 participants. Of note is the wide variation in time post stroke onset ranging from 31-1369 (mean 174.6 days; SD 272.2) days post stroke in control sites and 17-1105 days (mean 169.7; SD 238.3) post stroke in intervention sites. Demographic variables including ethnicity and social circumstances were comparable between intervention and control sites, with the exception of age (Table 2). Baseline data were complete for 74/78 participants (95%; 95%CI 87% to 99%) and there was no significant difference between the study arms for this (p=0.35, Fisher's exact test).

Table 2. Characteristics of study participants

		Intervention (n=40)	Control (n=38)
Age		61.79±16.03	68.82±10.28
Sex	Male	20 (50%)	25 (65.8%)
	Female	20 (50%)	13 (34.2%)
Time post stroke onset (days)	Min, max	31, 1369	17, 1105
	Mean	238.3 days	169.7
Cohabitants	Living alone	11/38	11/37
	Spouse only	18/38	20/37
	Others	9/38	6/37
Carers	None	4/38	6/37
	Professional	9/38	11/37
	Family and friends only	25/38	20/37
Housing	House	21/38	23/37
	Apartment	15/38	9/37
	Other	2/38	5/37
Ethnicity	White British	17/38	19/37
	Other White	3/38	8/37
	Black Caribbean	10/38	6/37
	Other	8/38	4/37

NEADL	29.89±14.38	30.78±17.01
HADS-A	7.54±5.27	7.43±5.10
HADS-D	6.90±4.22	7.11±3.44
SAQOL mean	3.37±0.77	3.25±0.81
SAQOL physical	3.40±0.87	3.05±1.05
SAQOL communication	4.00±1.08	4.09±0.90
SAQOL psychological	3.05 ± 1.00	3.01±1.01
SF-12 physical	34.00±8.53	30.86±10.10
SF-12 mental	46.84±12.57	40.96±14.24
SSEQ	25.95±8.64	23.51±9.72

Values are demographic (proportion) and baseline scores (mean±SD); NEADL, Nottingham Extended Activities of Daily Living scale; HADS-A, Hospital Anxiety and Depression Scale – Anxiety scores; HADS-D, Hospital Anxiety and Depression Scale – Depression scores; SAQOL, Stroke and Aphasia Quality of Life scores; SF-12, Short Form 12 questionnaire; SSEQ, Stroke Self-Efficacy Questionnaire

Clinical outcomes

Table 3 shows clinical data at 12 weeks completed for 66/78 participants (85%; 95%CI 75% to 92%) and there was no significant difference in outcomes between the arms of the trial for this (p=0.22, Fisher's exact test). The modelling revealed no significant difference between intervention and controls on any outcome that was tested, although the intervention sites showed more consistent improvement in self-efficacy (SSEQ) and functional capacity (NEADL) than control sites. If the intervention is aimed at changing self-efficacy and confidence to self-manage, then functional capacity, which measures actual performance, could be a feasible clinical endpoint in a future fully powered trial.

Outcome	Difference	Change	Change	Multilevel model

Table 3. Outcomes analysis

	at 12 weeks	from baseline	adjusted for age			
				Change at 6 weeks, adjusted for age	Change at 12 weeks, adjusted for age	Composite p-value
NEADL	3.47	4.37	3.77	2.89	4.51	0.14
HADS-A*	-0.85	-0.61	-0.23	-0.06	-0.45	0.87
HADS-D*	-0.96	-0.55	-0.38	-0.93	-0.59	0.36
SAQOL mean	0.26	0.05	0.02	0.02	0.05	0.91
SAQOL physical	0.32	-0.10	-0.09	-0.03	-0.08	0.87
SAQOL communication	0.15	0.17	0.14	0.13	0.16	0.52
SAQOL psychological	0.26	0.15	0.08	0.04	0.14	0.72
SF-12 physical	3.13	-0.31	-0.37	0.61	-0.07	0.91
SF-12 mental	3.36	-1.16	-1.77	-3.92	-2.20	0.31
SSEQ	4.83	1.91	1.11	2.20	2.17	0.30

Values are expressed as mean differences between intervention and control sites. Output from the multilevel model comparing changes (adjusted for age) across collected outcome measures.
NEADL, Nottingham Extended Activities of Daily Living scale; HADS-A, Hospital Anxiety and Depression Scale – Anxiety scores; HADS-D, Hospital Anxiety and Depression Scale – Depression scores; SAQOL, Stroke and Aphasia Quality of Life scores; SF-12, Short Form 12 questionnaire; SSEQ, Stroke Self-Efficacy Questionnaire.

*high scores on HADS indicate worse morbidity, for all other scales this is reversed

Sample size calculation for a definitive study

A sample size calculation for a future cluster randomised controlled trial can be based on the NEADL at 12 weeks based on minimum clinically important differences (MCID) suggested as 6.1. The mean (SD) for NEADL was 35.5 (16.86) in the intervention group and 32.1 (19.05) in the control group, and Pearson correlation between baseline and twelve week follow-up NEADL was 0.78. Sites in this study were similar for NEADL apart from one site which had a lower mean (but this seems to have been driven by just two participants), therefore we assumed that intra-class correlation can be set to zero in the sample size calculation. This effectively uses a sample size calculation for parallel-arms randomised controlled trials. The MCID for NEADL would require 137 in each arm. Assuming a pessimistic completion rate at twelve weeks of 75%, the lower end of the confidence interval from this study's data, this requires consenting 183 participants per arm for NEADL. Realistically, twenty participants can be recruited and assessed per site over 10 months, so this implies allocating 9 sites per arm for NEADL alone.

Resources and costs of the intervention

Total rehabilitation inputs were similar in the two control sites (24 therapy hours per patient). However a large difference was found between the two intervention sites (20.1 vs 50.7

therapy hours), with a proportionally higher use of therapy assistants in the lower resource use group. Costs of patient facing time ranged from £600 in the low resource use intervention site to £1667 in the high resource use intervention site. The costs of the two control sites were similar (£754 and £763). Total costs for control sites (mean of two sites) ranged from £930 to £1459, depending on the assumptions made about the ratios of patient facing to patient-related non face-to-face costs. The equivalent range for the low resource use intervention site was £721 to £1103, and for the high resource use intervention site was £1987 to £3012 (Table 4).

Table 4. Resources and costs* used in delivering rehabilitation in the four sites

Mean (SD)		**Intervention sites**		**Control sites**	
Min/Range		**Cluster 1**	**Cluster 2**	**Cluster 3**	**Cluster 4**
Mean cost £					
Number of patients		15	23	13	22
Hours of face-to-face contact	OT	10.53 (5.28)	5.03 (4.92)	6.89 (5.11)	6.63 (8.54)
		5/15	0/17	0/14	0/34.1
		£347.60	£165.96	£227.45	£218.87
	PT	14.12 (14.56)	5.08 (5.20)	5.33 (5.19)	9.02 (7.15)
		0/55	0/18	0/14	0/22.1
		£465.80	£167.51	£175.92	£297.75
	SLT	6.33 (8.45)	2.17 (4.91)	6.32 (8.43)	1.62 (13.89)
		0/30	0/19	0/24.3	0/65.1
		£209.00	£71.74	£208.66	£152.37
	TA	25.78 (23.08)	7.81 (11.10)	5.69 (7.35)	1.77 (4.76)
		0/76.5	0/45.75	0/23	0/16.2
		£644.58	£195.20	£142.31	£94.22
	Mean total hours	56.77	20.09	24.24	24.04
	Hours by TA	45.4%	38.8%	23.6%	15.6%
Mean total cost of face-to-face contact time		**£1667**	**£600**	**£754**	**£763**
% of total face-to-face		38.7%	32.5%	18.9%	12.3%

cost due to TA					
Mean total	High estimate	£1345	£503	£683	£716
cost patient-	1:1 for AHPs				
related non	1:0.5 for TA	**(£3012)**	**(£1103)**	**(£1438)**	**(£1479)**
face-to-face	Middle	£672	£251	£342	£358
contact time	estimate				
(Total cost:	1:0.5 for	**(£2339)**	**(£851)**	**(£1096)**	**(£1121)**
sum face-to-	AHPs				
face and non	1:0.25 for TA				
face-to-face)	Low estimate	£320	£121	£167	£177
	1:0.25 for				
	AHPs	**(£1987)**	**(£721)**	**(£921)**	**(£940)**
	1:0.25 for TA				

*Patient contact costs per hour:[41] Occupational Therapy (OT), Physiotherapy (PT), Speech and Language Therapy (SLT) = £33; Technical Assistant grade (TA) = £25

Patient level use of other health and social services at 6 and 12 week follow up were available for 64 of the 73 (88%) participants; the remainder were either lost to follow up or withdrew. There were relatively few missing data items. The only services used by more than 10% of respondents were GPs, nurses, hospital outpatient and emergency departments; (data not shown); all other services, including social care, were not accessed by more than 90% or participants. Comparisons between sites of total costs of other service utilisation revealed no significant differences between any pair of sites. However, when only stroke-related service use was considered, the other health and social service costs of patients in the low cost intervention site were higher than in the other sites, and significantly higher than in one of the control sites (mean total cost of stroke-related health service use, excluding inpatient care £259.10 vs. £126.90, Mann Whitney U (MWU) p= 0.017; mean total costs of stroke-related health (excluding inpatient) and social service (excluding self-paid) utilisation £756.45 vs. £451.17, MWU p= 0.06).

DISCUSSION

This is the first study to test the feasibility of conducting a cluster randomised controlled trial into the effectiveness of a stroke SMP integrated into post hospital rehabilitation. Overall the design using a nested process evaluation was found to be feasible and the intervention was delivered according to pre-determined markers of fidelity.

Recruitment rate at 25%, was higher than previous research (18%).[24] But patients who required fewer than six sessions were the main reason for exclusion (58%). This is a limitation of this study and our previous research, but was chosen following discussion with CSR teams based on the premise that patients requiring less than six would be less likely to have ongoing rehabilitation needs and would usually be managed by assessment and one-off advice. However further research to adapt self-management interventions to be delivered in fewer number of sessions whilst delivering the same impact, such as that developed by Harwood and colleagues are now warranted.[34] Participants with aphasia and other cognitive impairments were also recruited at a lower rate and previous research using provider-based stroke SMPs has included low numbers of people with aphasia.[9] . Participants were also excluded due to low mood, not engaging in therapy and social issues, and twelve potential participants were excluded with no clear reason other than they were less compliant or more challenging. We suspect there were issues of potential gate keeping and selection of 'model' participants for the trial illustrated in other studies,[35] which highlight the need for training to include methods and practical solutions of extending the SMP to more patients.

Outcomes measuring functional capacity (NEADL) and self-efficacy (SSEQ) showed most sensitivity to change in the intervention compared to control sites. This provides some validation of the aims of Bridges Stroke SMP which uses self-efficacy principles to facilitate a change in functional capacity and self-management. Functional capacity and mood have

been shown to be closely associated with self-efficacy post stroke, but the causal relationship has not been established.[11, 36] However we suggest a measure of functional capacity such as the NEADL as a primary outcome with secondary measures of mood, quality of life and self-efficacy are warranted in future self-management trials. At least 18 clusters would be required recruiting 20 participants per site to evaluate effectiveness of this stroke SMP in a full trial.

A number of economic findings were relevant to a full trial. In particular, the resource implications of the intervention appeared very different in the two sites, and needs to be further explored. The tool for collecting data on other service use worked well, but the burden on participants might be reduced by concentrating on services (including GP and nurse) used most frequently, and only on those that were stroke-related. The SF-12 scores were not significantly different between groups so QALYs were not calculated, although a larger trial may identify differences.

The quality of training given to clinicians in the intervention sites was central to the delivery of the SMP as intended, but was more labour intensive than expected due to high staff turnover. However compared to recent large scale trials of provider-based self-management programmes,[37-39] clinicians from the intervention sites engaged in training, and enacted behaviours aligned with pre-determined markers of self-management support. Nonetheless training costs are a major consideration for SMP implementation, and less costly methods of training such as on-line resources and peer learning utilising SMP champions could be employed in a full trial.

Overall the study was completed with minimal data lost to follow up and the trial design could be replicated in a larger definitive trial. However furthur consideration of criteria such as requiring more than six sessions of rehabilitation is needed and consideration of how to

ensure that SMPs are accessible to more patients with cognitive and communication impairments. These results support the need for conducting further research in this area and provide data to support the design of a definitive trial.

Acknowledgements

We acknowledge the input from our stakeholder reference and expert advisory groups; support from the Collaboration for Leadership in Applied Health Research and Care (CLAHRC) South London; and Professor Charles Wolfe for his help with early drafts of this paper.

Funding

This report presents independent research funded by the National Institute for Health Research (Research for Patient Benefit Programme; Grant Number: PB-PG-0610-22276). The views expressed in the publication are those of the authors and not necessarily those of the NHS, the National Institute for Health Research or the Department of Health.

Additional financial support for the study was provided by London (South) Comprehensive Research Network.

Contributors

All authors designed the study. FJ, RG, HG and ML performed data analysis, FJ, ML wrote initial draft and all authors commented on the manuscript.

Competing interests

FJ is the founder and director of the social enterprise Bridges self-management

Ethical approval

The London Surrey Borders National Research Ethics Committee gave ethical approval for this study (11/LO/1450) with local Research & Development approval granted from each of the cluster sites.

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	Page 1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Page 3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	pages 5 and 6
	2b	Specific objectives or hypotheses	page 6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	page 7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	none
Participants	4a	Eligibility criteria for participants	page 7 and 11
	4b	Settings and locations where the data were collected	page 7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	pages 8-10
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	page 13
	6b	Any changes to trial outcomes after the trial commenced, with reasons	none
Sample size	7a	How sample size was determined	page 12 and 13

	7b	When applicable, explanation of any interim analyses and stopping guidelines	not applicable
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	page 7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	page 7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	page 7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	page 7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	page 12
	11b	If relevant, description of the similarity of interventions	page 11
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	page 13
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	page 13 and 14
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	page 17
	13b	For each group, losses and exclusions after randomisation, together with reasons	page 17
Recruitment	14a	Dates defining the periods of recruitment and follow-up	page 16
	14b	Why the trial ended or was stopped	n/a

Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	page 19
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	page 19, 20
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	page 19,20
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	n/a
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	page 19, 20
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	none
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	page 27
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	n/a
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	page 27,28
Other information			
Registration	23	Registration number and name of trial registry	page 4
Protocol	24	Where the full trial protocol can be accessed, if available	not available
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	page 29

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

A feasibility study of an integrated stroke self-management programme: a cluster randomised controlled trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2015-008900.R1
Article Type:	Research
Date Submitted by the Author:	09-Sep-2015
Complete List of Authors:	Jones, Fiona; Kingston University and St George's University of London, Faculty of Health, Social Care and Education Gage, Heather; University of Surrey, School of Economics Drummond, Avril; University of Nottingham, Div of Rehabilitation and Ageing Bhalla, Ajay; Guy's & St Thomas NHS Foundation Trust, Division of Health and Ageing Grant, Robert; Kingston University and St George's University of London, Faculty of Health, Social Care and Education Lennon, Sheila; Flinders University, School of Health Sciences McKevitt, Christopher; King's College London, Division of Health & Social Care Research, and NIHR Biomedical Research Centre at Guy's and St Thomas' NHS Foundation Trust Riazi, Afsane; Royal Holloway, University of London, Department of Psychology Liston, Matthew; Kingston University and St George's University of London, Faculty of Health , Social Care and Education
Primary Subject Heading:	Rehabilitation medicine
Secondary Subject Heading:	Patient-centred medicine, Neurology
Keywords:	Stroke < NEUROLOGY, REHABILITATION MEDICINE, PUBLIC HEALTH

Title: A feasibility study of an integrated stroke self-management programme: a cluster randomised controlled trial

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Cover title: Self-management in stroke rehabilitation

Tables:

Figures:

Key words: Self-management, Stroke, Rehabilitation

ABSTRACT

Objectives: To test the feasibility of conducting a controlled trial into the effectiveness of a self-management programme integrated into stroke rehabilitation.

Design: A feasibility cluster randomised design was utilised with stroke rehabilitation teams as units of randomisation.

Setting: Community based stroke rehabilitation teams in London.

Participants: 78 patients with a diagnosis of stroke requiring community based rehabilitation

Intervention: The intervention consisted of an individualised approach to self-management based on self-efficacy. Clinicians were trained to integrate defined self-management principles into scheduled rehabilitation sessions, supported by a patient-held workbook.

Main Outcomes measures: Patient measures of quality of life, mood, self-efficacy and functional capacity and health and social care utilisation were carried out by blinded assessors at baseline, six weeks and 12 weeks. Fidelity and acceptability of the delivery was evaluated by observation and interviews.

Results: Four community stroke rehabilitation teams were recruited, and received a total of 317 stroke referrals over 14 months. Of these 138 met trial eligibility criteria and 78 participants were recruited (56.5%). Demographic and baseline outcome measures were similar between intervention and control arms, with the exception of age. All outcomes measures were feasible to use and clinical data at 12 weeks was completed for 66/78 participants (85%; 95%CI 75% to 92%). There was no significant difference in any of the outcomes between the arms of the trial, but measures of functional capacity and self-efficacy showed responsiveness to the intervention . Observation and interview data confirmed

acceptibility and fidelity of delivery according to pre-determined criteria. Costs varied by site.

Conclusions: It was feasible to integrate a stroke self-management programme into community rehabilitation using key principles. Some data were lost to follow up but overall results support the need for conducting further research in this area and provide data to support the design of a definitive trial.

Clinical Trial Registration-URL: http://www.controlled –trials.com. Unique identifier: ISRCTN42534180

Strengths and Limitations

- This is the first feasibility trial of an integrated approach to stroke self-management, study recruitment and findings support further research to test the intervention in a definitive trial
- Community stroke rehabilitation teams had a high turnover of staff and training needs were higher than anticipated but intervention fidelity was maintained
- The intervention requires some modification to be more accessible for those patients with cognitive and communication impairments and those having less than six sessions of rehabilitation.

INTRODUCTION

Significant improvements have been made in the quality and effectiveness of acute stroke care across the developed world.[1-3] But variation in the availability of post hospital rehabilitation and support for self-managed activities still exists,[3-4] and the prevalence of mood disorders and social isolation post stroke remains high.[5-7] As the overall global burden of stroke increases,[1] expenditure on the direct and indirect costs of stroke care is likely to rise, and in the United Kingdom (UK) this currently constitutes 5% of the total National Health Service (NHS) budget (£8 billion).[8] Stroke and associated care models are still largely defined by acute medical ideologies and there is an inequity in attention to address long term psychological and social sequelae.[9-11] Arguably unmet needs post stroke could be exacerbated by care models which foster dependency on professional expertise in the acute stages combined with a paucity of programmes to facilitate coping and self-management in the longer term.

One alternative to existing care models is the use of self-management programmes (SMPs) which build on growing evidence from systematic reviews in other long-term conditions.[12-15] SMPs can be 'provider-based' delivered by healthcare professionals integrated into usual care or 'patient-based' when supplied in addition to care through group or individual education.[13-16] Broadly self-management focuses on those actions individuals and others take to mitigate the effects of a long term condition and to maintain the best possible quality of life.[12-14] The variation in programmes makes it difficult to compare outcomes, but effective SMPs can improve mental wellbeing, quality of life and reduce hospital readmission rates.[12-16]

The UK National Stroke Strategy in 2007 advocated self-management initiatives to address long term unmet needs,[17] and national guidance recommends that all patients be offered training in self-management skills.[18] Research to develop and evaluate stroke SMPs mainly

comprises feasibility and phase II trials of group based programmes, which, whilst demonstrating some impact on function, mood and quality of life,[9, 19, 20] will not be accessible for certain patients with communication and cognitive impairments.[21] We hypothesised that an individualised stroke self-management intervention which can be integrated into existing rehabilitation may extend the reach to more patients.[11, 19,22]

Following the Medical Research Council Framework for the Development and Evaluation of Complex Interventions [23] several studies have been conducted to inform the development of an individualised SMP.[22, 24] The Bridges Stroke SMP is based on social cognition theory and self-efficacy[25, 26] and incorporates a patient held workbook used by rehabilitation professionals to support self-management skills. Studies have demonstrated preliminary proof of concept and feasibility when provided in addition to rehabilitation.[22, 24.] However a SMP delivered in addition to routine stroke rehabilitation has cost and time implications, especially when utilising an individualised approach. If the same programme could be integrated into existing rehabilitation this may offer a solution which could be both clinically and cost-effective.

The aim of the study was to test the feasibility of conducting a cluster randomised controlled trial into the effectiveness of a stroke SMP (Bridges) integrated into community rehabilitation. We aimed to evaluate key trial parameters such as recruitment and retention of participants, randomisation, utility and sensitivity of outcome measures, levels of missing data, and preliminary indications of effectiveness to inform calculation of a sample size for powering a full trial. An estimation of resources required to deliver the intervention and indications of likely cost effectiveness were also investigated. Fidelity of the intervention delivery, training required and acceptability of the intervention to patients and clinicians was evaluated.

METHODS

Design

A feasibility cluster randomised design with a nested process evaluation was utilised with community stroke rehabilitation (CSR) teams as units of randomisation. Sites were eligible if they comprised multiprofessional teams with stroke specialist skills delivering post hospital rehabilitation according to quality criteria set out in UK National Clinical Guidelines for Stroke.[18] Current models of CSR in the UK provide rehabilitation by therapists (occupational therapists, physiotherapists and speech and language therapists) and non-professional support workers in patients' homes.

Ethical approval

The London Surrey Borders National Research Ethics Committee gave ethical approval for this study (11/LO/1450) with local Research & Development approval granted from each of the cluster sites.

Selection of sites

Twenty–one CSR teams from outer and inner London boroughs with ethnically and socially diverse populations were sent information about the study via a group email used for a pan-London Stroke Rehabilitation Network. Six teams agreed to take part and four teams were selected as they had not taken part in any previous self-management training in the previous 12 months and met all other eligibility criteria. Team consent was obtained from the lead clinician acting as a cluster guardian.

Randomisation

Allocation of CSR teams to either an intervention or control cluster was carried out once teams had been recruited and given consent to participate by a local clinical trials unit via simple randomisation at 1:1 ratio without matching.

Intervention

Intervention site teams undertook training on theory, research and practical application of the Bridges SMP. Training delivery in intervention sites adhered to a pre-determined protocol based on seven key principles of the SMP; these were developed through previous research and in consultation with key stakeholders (Table 1). [22,24]

Table 1. Seven key principles of the Bridges stroke self-management programme

Key Principle	An example of what might be observed to demonstrate use of key principle
Problem solving Not being given solutions but encouraged to come up with ideas and strategies	Clinician reminds patient about how they have found ways around a problem or challenge before e.g. "I remember when you had to work really hard to do 'x' – how did you manage that, is there any way you can use the same skills now?"
Reflection Attributing changes and progress to personal effort/not skills of therapist	Clinician encourages regular reflection in workbook to capture changes and how progress is being made e.g. Highlighting the value of reflecting on progress: "It will help to have a reminder about all the things you have managed to do, however small"
Goal setting Avoiding therapy-led goals, encouraging small steps for mastery experiences and longer term goals	Patient is encouraged to think of small things they could do towards their goal, instead of being discouraged from an 'unrealistic target' e.g. "What's a small thing you could do this week that might help you towards that?"
Accessing resources Using resources available to achieve personal goals	Clinician uses open style coaching questions e.g. "What support could you use to help you get to that?"

Self-discovery Finding out new ways of doing things and trying out different activities	Clinician asks about the ways the patient managed to do challenging things before their stroke and what strategies that have worked for them previously e.g. Clinician is heard discussing the need to take some risks, and try things out- and the benefit to learning about what is possible
Activity Encouraging any activity however small	Clinician asks what they have managed to do in the last week, what they are most pleased with in terms of their activity e.g. "What have you managed to do in the past week that you are really pleased about?"
Knowledge Knowledge about stroke, but also about self	Clinician explores what the patient knows about their stroke, what they would like to know and any concerns that patient feels might be hampering rehabilitation e.g. "Are there any things that you are worried might be affecting your rehab? Is there one small thing we can work towards that might help?"

The Bridges SMP aimed to be distinct from routine stroke rehabilitation provision in two main ways;

1. One-to-one rehabilitation sessions using seven principles integrated into each therapy session to support self-management activities.
2. A stroke workbook which included vignettes, activities, ideas and solutions from other stroke survivors for successful self-management and space to record and reflect on goals and progress.

Recruitment

Consecutive stroke patients referred for CSR were screened by the community rehabilitation teams, recruited within two weeks of referral to the CSR team, and consented by research staff not blinded to allocation. Patients were eligible if they had a confirmed diagnosis of stroke and could follow-a two stage command such as close your eyes and nod your head, and read simple text and/or have a carer to assist. Criteria were informed by previous research.[22, 24]

Stroke participants allocated to the intervention clusters were introduced to the stroke workbook and the seven key principles of self-management by the therapist integrated into existing CSR sessions. Participants in control sites received CSR as usual, which included access to physiotherapy, occupational therapy and speech and language therapy if required.

Sample size

As this was a feasibility study, a prospective sample size calculation was not conducted. We aimed to recruit 80 stroke participants across the four sites over 14 months, which appeared realistic given the teams' referral rates.

Assessments

Data were collected in participants' homes by research assessors blinded to group allocation. Clinical outcomes were collected at baseline (within two weeks from commencing rehabilitation), six weeks and twelve weeks after baseline.

Feasibility, fidelity and acceptability

The feasibility of recruiting and retaining participants was assessed from study records, and characteristics of those who were not eligible, consent and completion rates were analysed. Participants' age, sex, social support, socioeconomic status and past medical history were described and compared between groups to test randomisation.

Fidelity and acceptability of the delivery of the intervention was determined by observing a proportion of rehabilitation sessions using a checklist to record patient and professional activities and behaviours against each principle component of the SMP. The checklist was piloted to enable a method to compare self-management support delivered in intervention and control sites that could be used in a larger trial. Patients and clinicians were interviewed in each site to compare their experiences and understanding of self-management; those in the

intervention site were specifically asked about the feasibility and acceptability of using self-management strategies and workbook.

Clinical outcomes

Clinical measures found sensitive to change in previous self-management trials and validated in stroke populations were utilised [9, 20, 24] and included the Stroke and Aphasia Quality of Life (SAQOL) scale,[27] Nottingham Extended Activities of Daily Living Scale (NEADL) of functional ability,[28] Stroke Self-Efficacy Questionnaire (SSEQ)[29, 30] and Hospital Anxiety and Depression Scale (HAD).[31] The Medical Outcomes Trust's Short Form 12 (SF12) was included to provide a generic measure health related quality of life.[32] Ease of data capture and levels of missing data were assessed for each outcome measure.

Although the study was not powered, a statistical analysis was conducted to gain a preliminary indication of effectiveness and of the feasibility of such analysis. The analysis enabled an assessment of the sensitivity of different outcome measures and provided a basis for a sample size calculation for the full trial.

Statistical Analysis

Considering feasibility, we compared levels of missing data between intervention and control sites using Fisher's exact test. In order to adjust for age, a multilevel regression model was fitted to each clinical outcome. This is a common approach to cluster randomised clinical trials, and utilises all data, even if a participant is missing some. Group allocation was purely on the basis of site, forming an intention-to-treat analysis. Inter-participant variability was represented as a random intercept, and age, time and group allocation were included as fixed

effects. Group differences were quantified at six and twelve weeks, and a composite null hypothesis that both were equal to zero was assessed by Wald tests. This represents no mean difference between groups in how the outcomes change over time. These analyses were conducted in Stata version 11.2 software (StataCorp, College Station, TX) using command 'xtmixed'.

Sample size calculations for a future trial were calculated using Stata software (command 'sampsi'), assuming standard deviations observed in this study for NEADL and SAQOL, 80% power requirement, and a range of putative minimum clinically important differences: NEADL from 2 to 5 in steps of 0.1, and SAQOL from 0.1 to 0.5 in steps of 0.01.

Economic analysis

To estimate the resources involved in delivering stoke rehabilitation in each site, data were collected at individual patient level from therapist records on the number of CSR sessions, and face-to-face contact time in minutes. Physical resources were converted to costs using validated national unit costs [33] . Costs associated with patient-related non face-to-face time was calculated under three alternative assumptions, Total costs were compared across sites.

The feasibility of capturing health and social care utilisation from participants was assessed using a bespoke self-report questionnaire administered to participants at week 6 and 12. Items included contacts with General Clinician (GP), practice nurse or other professionals, social care and help from family and friends. The purpose was to explore if use of SMP reduced demands on other services, compared to the control group. EQ-5D health state utility weights, using a published transformation[33] of the SF-12 profile measure of quality of life, was to be tested for deriving quality adjusted life year (QALY) gains.

RESULTS

Intervention fidelity and acceptability

Overall 63 occupational therapists, physiotherapists, speech and language therapists and rehabilitation support workers, received training. This number was higher than expected because of clinician turnover.

The feasibility of monitoring intervention fidelity was evaluated through observations of a consecutive sample of 14 participants (18%, control n=7, intervention n=7). The checklist was feasible to use and identified whether CSR incorporated behaviours and activities relating to core self-management principles. Clinicians in the intervention sites showed use of between five to seven self-management principles, whereas those in the control site showed evidence of using two or less.

A consecutive sample of patients (n=23) were interviewed and focus groups were carried out with all clinicians (n=34) including occupational therapists, physiotherapists, speech and language therapists and rehabilitation support workers across sites at the end of the trial to explore intervention feasibility and acceptability. Findings showed shared understandings of self-management in patients and clinicians within the intervention clusters, which reflected the underlying principles of the SMP and will be reported more fully elsewhere.

Feasibility

Recruitment rates: Four sites were recruited from six CSR teams in London that expressed an interest and were eligible, excluded sites had either previously taken part in self-management training or were likely to undergo significant re-organisation during the trial period of 22 months. Participant recruitment occurred between July 2012 and August 2013,

138/317 patients (44%) were eligible to participate across four sites. Recruitment took 14 months which was longer than the anticipated 10 months. This was due to restructuring of some community services and a requirement for further training for new staff. Of those eligible and invited to participate, 78/138 (56%) consented and were recruited to the trial (at a rate of 5.57/month). Control sites recruited n=38 compared to n=40 in intervention sites. The main reason for non-eligibility were patients not requiring six rehabilitation sessions or more (58%), and patients with cognitive and communication impairments (17%). The latter were excluded as a certain minimum level of cognitive and communication ability (i.e. ability to follow a verbal or non-verbal two-stage command) was required for the intervention, which is based on cognitive interaction between practitioner and stroke survivor.

Completion rates

The research protocol was successfully delivered and outcome assessors remained blinded to the intervention throughout the duration of the trial. Figure 1 shows rates of completion varied slightly between control and intervention sites. Thirty-nine participants (98%) completed baseline measures and 36 participants completed week 12 outcome measures (90%) in intervention sites, compared to 35 (92%) completing baseline outcomes and 30 (79%) competing week 12 outcomes measures in control sites. Reasons for withdrawal included ill health, change in family circumstances with only three cases of withdrawal due to burden of outcome measurement (nature of the questions (n=1) and the volume of questions (n=2)).

Figure 1. Study flow diagram

Insert here

Randomisation

Participant characteristics

Table 2 shows an even distribution of men and women in intervention sites but more men took part in the control sites. Days post stroke data were missing in 8/78 participants. Of note is the wide variation in the length of time since stroke onset. Demographic variables including ethnicity and social circumstances were comparable between intervention and control sites, with the exception of age. Baseline data were complete for 74 (95%) out of 78 participants (95%CI: 87% to 99%), with no significant difference between study arms (98% intervention vs 92% control, p=0.35, Fisher's exact test).

Table 2. Characteristics of study participants

		Intervention (n=40)	Control (n=38)
Age		61.79±16.03	68.82±10.28
Sex	Male	20 (50%)	25 (65.8%)
	Female	20 (50%)	13 (34.2%)
Time post stroke onset (days)	Min, max	31, 1369	17, 1105
	Median (Inter-quartile range)	76 (44.5 to 130.5)	116 (46 to 170.5)
Cohabitants	Living alone	11/38 (29%)	11/37 (30%)
	Spouse only	18/38 (47%)	20/37 (54%)
	Others	9/38 (24%)	6/37 (16%)
Carers	None	4/38 (10%)	6/37 (16%)
	Professional	9/38 (24%)	11/37 (30%)
	Family and friends only	25/38 (66%)	20/37 (54%)
Housing	House	21/38 (55%)	23/37 (62%)
	Apartment	15/38 (40%)	9/37 (24%)
	Other	2/38 (5%)	5/37 (14%)
Ethnicity	White British	17/38 (45%)	19/37 (51%)
	Other White	3/38 (8%)	8/37 (22%)
	Black Caribbean	10/38 (26%)	6/37 (16%)
	Other	8/38 (21%)	4/37 (11%)
NEADL		29.89±14.38	30.78±17.01
HADS-A		7.54±5.27	7.43±5.10
HADS-D		6.90±4.22	7.11±3.44
SAQOL mean		3.37±0.77	3.25±0.81
SAQOL physical		3.40±0.87	3.05±1.05
SAQOL communication		4.00±1.08	4.09±0.90
SAQOL psychological		3.05±1.00	3.01±1.01
SF-12 physical		34.00±8.53	30.86±10.10
SF-12 mental		46.84±12.57	40.96±14.24
SSEQ		25.95±8.64	23.51±9.72

Values are proportion (percentage) or mean±SD, unless otherwise indicated; NEADL, Nottingham Extended Activities of Daily Living scale; HADS-A, Hospital Anxiety and Depression Scale – Anxiety scores; HADS-D, Hospital Anxiety and Depression Scale – Depression scores; SAQOL, Stroke and Aphasia Quality of Life scores; SF-12, Short Form 12 questionnaire; SSEQ, Stroke Self-Efficacy Questionnaire

Clinical outcomes

Table 3 shows means and standard deviations for all outcomes at each time point (baseline, six weeks and 12 weeks). Table 3 shows clinical data at 12 weeks completed for 65/78 participants (83%; 95%CI 75% to 92%), and there was no significant difference in outcomes between the arms of the trial for this (p=0.22, Fisher's exact test). The modelling revealed no significant difference between intervention and controls on any outcome that was tested, although the intervention sites showed more consistent improvement in self-efficacy (SSEQ) and functional capacity (NEADL) than control sites (Table 4). If the intervention is aimed at changing self-efficacy and confidence to self-manage, then functional capacity, which measures actual performance, could be a feasible clinical endpoint in a future fully powered trial.

Table 3. Means and Standard deviations of outcomes at all time points

Outcome	Intervention group (n=2)			Control group (n=2)		
	Baseline	6 weeks	12 weeks	Baseline	6 weeks	12 weeks
NEADL	29.9±14.4	32.6±16.4	35.5±16.9	30.8±17.0	31.5±18.5	32.1±19.0
HADS-A*	7.5±5.3	7.5±4.9	6.6±5.3	7.4±5.1	7.3±4.9	7.4±4.5
HADS-D*	6.9±4.2	7.1±4.5	7.1±4.3	7.1±3.4	8.2±4.1	8.1±4.1
SAQOL mean	3.4±0.8	3.3±0.8	3.4±0.8	3.2±0.8	3.2±0.7	3.1±0.8
SAQOL physical	3.4±0.9	3.3±1.0	3.4±1.0	3.1±1.1	3.1±1.0	3.0±1.1
SAQOL communication	4.0±1.1	4.0±1.0	4.2±1.1	4.1±0.9	3.9±1.0	4.0±0.9
SAQOL psychological	3.1±1.0	3.0±1.0	3.1±1.1	3.0±1.0	3.0±0.9	2.8±0.9
SF-12 physical	34.0±8.5	34.9±10.0	36.3±10.8	30.9±10.1	31.6±7.0	33.1±8.8
SF-12 mental	46.8±12.6	45.5±11.8	46.1±10.7	41.0±14.2	44.7±13.1	42.8±11.9
SSEQ	25.9±8.6	25.7±9.4	26.4±9.0	23.5±9.7	21.3±9.2	21.5±10.6

NEADL, Nottingham Extended Activities of Daily Living scale; HADS-A, Hospital Anxiety and Depression Scale – Anxiety scores; HADS-D, Hospital Anxiety and Depression Scale – Depression scores; SAQOL, Stroke and Aphasia Quality of Life scores; SF-12, Short Form 12 questionnaire; SSEQ, Stroke Self-Efficacy Questionnaire.
*high scores on HADS indicate worse morbidity, for all other scales this is reversed

Table 4. Outcomes analysis

Outcome	Difference at 12 weeks	Change from baseline	Change adjusted for age	Multilevel model		
				Change at 6 weeks, adjusted for age	Change at 12 weeks, adjusted for age	Composite p-value
NEADL	3.47	4.37	3.77	2.89	4.51	0.14
HADS-A*	-0.85	-0.61	-0.23	-0.06	-0.45	0.87
HADS-D*	-0.96	-0.55	-0.38	-0.93	-0.59	0.36
SAQOL mean	0.26	0.05	0.02	0.02	0.05	0.91
SAQOL physical	0.32	-0.10	-0.09	-0.03	-0.08	0.87
SAQOL communication	0.15	0.17	0.14	0.13	0.16	0.52
SAQOL psychological	0.26	0.15	0.08	0.04	0.14	0.72
SF-12 physical	3.13	-0.31	-0.37	0.61	-0.07	0.91
SF-12 mental	3.36	-1.16	-1.77	-3.92	-2.20	0.31
SSEQ	4.83	1.91	1.11	2.20	2.17	0.30

Values are expressed as mean differences between intervention and control sites. Output from the multilevel model comparing changes (adjusted for age) across collected outcome measures.
NEADL, Nottingham Extended Activities of Daily Living scale; HADS-A, Hospital Anxiety and Depression Scale – Anxiety scores; HADS-D, Hospital Anxiety and Depression Scale – Depression scores; SAQOL, Stroke and Aphasia Quality of Life scores; SF-12, Short Form 12 questionnaire; SSEQ, Stroke Self-Efficacy Questionnaire.
*high scores on HADS indicate worse morbidity, for all other scales this is reversed

Sample size calculation for a definitive study

A sample size calculation for a future cluster randomised controlled trial can be based on the NEADL at 12 weeks with minimum clinically important differences (MCID) suggested as 6.1. The mean (SD) for NEADL was 35.5 (16.86) in the intervention group and 32.1 (19.05) in the control group, and Pearson correlation between baseline and twelve week follow-up NEADL was 0.78. Sites in this study were similar for NEADL apart from one site which had a lower mean (but this seems to have been driven by just two participants), therefore we are not able to make a precise estimate of intra-class correlation for future studies, though it appears to be small. If we assume intra-class correlation of zero in the sample size calculation, this effectively uses a calculation for parallel-arms randomised controlled trials, and the MCID for NEADL would require 137 in each arm.[34] Assuming a pessimistic completion rate at twelve weeks of 75%, the lower end of the confidence interval from this study's data, this requires consenting 183 participants per arm for NEADL4, which implies allocating 9 sites per arm for NEADL alone.

Resources and costs of the intervention

Total rehabilitation inputs were similar in the two control sites (24 therapy hours per patient). However a difference was found between the two intervention sites (20.1 vs 50.7 therapy hours), with a proportionally higher use of therapy assistants in the lower resource use group. Costs of patient facing time ranged from £600 in the low resource use intervention site to £1667 in the high resource use intervention site. The costs of the two control sites were similar (£754 and £763). Total costs for control sites (mean of two sites) ranged from £930 to £1459, depending on the assumptions made about the ratios of patient facing to patient-related non face-to-face costs. The equivalent range for the low resource use intervention site

was £721 to £1103, and for the high resource use intervention site was £1987 to £3012 (Table 5).

Table 5. Resources and costs* used in delivering rehabilitation in the four sites

Mean (SD) Min/Range		**Intervention sites**		**Control sites**	
Mean cost £		**Cluster 1**	**Cluster 2**	**Cluster 3**	**Cluster 4**
Number of Patients (at 6 weeks)		14	23	19	12
Hours of face-to-face contact	OT	10.53 (5.28) 5/15 £347.60	5.03 (4.92) 0/17 £165.96	6.63 (8.54) 0/34.1 £218.87	6.89 (5.11) 0/14 £227.45
	PT	14.12 (14.56) 0/55 £465.80	5.08 (5.20) 0/18 £167.51	9.02 (7.15) 0/22.1 £297.75	5.33 (5.19) 0/14 £175.92
	SLT	6.33 (8.45) 0/30 £209.00	2.17 (4.91) 0/19 £71.74	1.62 (13.89) 0/65.1 £152.37	6.32 (8.43) 0/24.3 £208.66
	TA	25.78 (23.08) 0/76.5 £644.58	7.81 (11.10) 0/45.75 £195.20	1.77 (4.76) 0/16.2 £94.22	5.69 (7.35) 0/23 £142.31
	Mean total hours	56.77	20.09	24.04	24.24
	Hours by TA	45.4%	38.8%	15.6%	23.6%
Mean total cost of face-to-face contact time		**£1667**	**£600**	**£763**	**£754**
% of total face-to-face cost due to TA		38.7%	32.5%	12.3%	18.9%
Mean total cost patient-related non face-to-face contact time	High estimate 1:1 for AHPs 1:0.5 for TA	£1345 **(£3012)**	£503 **(£1103)**	£716 **(£1479)**	£683 **(£1438)**
	Middle estimate	£672	£251	£358	£342
(Total cost: sum face-to-face and non face-to-face)	1:0.5 for AHPs 1:0.25 for TA	**(£2339)**	**(£851)**	**(£1121)**	**(£1096)**
	Low estimate 1:0.25 for AHPs 1:0.25 for TA	£320 **(£1987)**	£121 **(£721)**	£177 **(£940)**	£167 **(£921)**

*Patient contact costs per hour:[33] Occupational Therapy (OT), Physiotherapy (PT), Speech and Language Therapy (SLT) = £33; Technical Assistant grade (TA) = £25

Patient level use of other health and social services at 6 and 12 week follow up were available for 63 of the 73 (88%) participants; the remainder were either lost to follow up or withdrew. There were relatively few missing data items. The only services used by more than 10% of respondents were GPs, nurses, hospital outpatient and emergency departments (data not shown); all other services, including social care, were not accessed by more than 90% or participants. Comparisons between sites of total costs of other service utilisation revealed no significant differences between any pair of sites. However, when only stroke-related service use was considered, the other health and social service costs of patients in the low cost intervention site were higher than in the other sites, and significantly higher than in one of the control sites (mean total cost of stroke-related health service use, excluding inpatient care £259.10 vs. £126.90, Mann Whitney U (MWU) p= 0.017; mean total costs of stroke-related health (excluding inpatient) and social service (excluding self-paid) utilisation £756.45 vs. £451.17, MWU p= 0.06).

DISCUSSION

This is the first study to test the feasibility of conducting a cluster randomised controlled trial into the effectiveness of a stroke SMP integrated into post hospital rehabilitation. Overall the design using a nested process evaluation was found to be feasible and the intervention was delivered according to pre-determined markers of fidelity.

Recruitment rate at 25%, was higher than previous research (18%).[24] But patients who required fewer than six sessions were the main reason for exclusion (58%). This is a limitation of this study and our previous research, but was chosen following discussion with CSR teams based on the premise that patients requiring less than six would be less likely to have ongoing rehabilitation needs and would usually be managed by assessment and one-off advice. However further research to adapt self-management interventions to be delivered in fewer number of sessions whilst delivering the same impact, such as that developed by Harwood and colleagues are now warranted.[35] Participants with aphasia and other cognitive impairments were also recruited at a lower rate and previous research using provider-based stroke SMPs has included low numbers of people with aphasia.[9] Participants were also excluded due to low mood, not engaging in therapy and social issues, and twelve potential participants were excluded with no clear reason other than they were less compliant or more challenging. We suspect there were issues of potential gate keeping and selection of 'model' participants for the trial illustrated in other studies,[36] which highlight the need for training to include methods and practical solutions of extending the SMP to more patients.

Outcomes measuring functional capacity (NEADL) and self-efficacy (SSEQ) showed most sensitivity to change in the intervention compared to control sites. This provides some validation of the aims of Bridges Stroke SMP which uses self-efficacy principles to facilitate a change in functional capacity and self-management. Functional capacity and mood have

been shown to be closely associated with self-efficacy post stroke, but the causal relationship has not been established.[11, 37] However we suggest a measure of functional capacity such as the NEADL as a primary outcome with secondary measures of mood, quality of life and self-efficacy are warranted in future self-management trials. At least 18 clusters would be required recruiting 20 participants per site to evaluate effectiveness of this stroke SMP in a full trial.

A number of economic findings were relevant to a full trial. In particular, the resource implications of the intervention appeared very different in the two sites. The composition of teams, particularly the ratio of professional to support staff, and relevant cost analyses require further evaluation. The tool for collecting data on other service use worked well, but the burden on participants might be reduced by concentrating on services (including GP and nurse) used most frequently, and only on those that were stroke-related. The SF-12 scores were not significantly different between groups so QALYs were not calculated, although a larger trial may identify differences.

The quality of training given to clinicians in the intervention sites was central to the delivery of the SMP as intended, but was more labour intensive than expected due to high staff turnover. However compared to recent large scale trials of provider-based self-management programmes,[38-40] clinicians from the intervention sites engaged in training, and enacted behaviours aligned with pre-determined markers of self-management support. Nonetheless training costs are a major consideration for SMP implementation, and less costly methods of training such as on-line resources and peer learning utilising SMP champions could be employed in a full trial.

Overall the study was completed with minimal data lost to follow up and the trial design could be replicated in a larger definitive trial. By reducing the number of sessions required,

addressing accessibility of the workbook and adapting the intervention for people with cognitive impairments recruitment rates could increase further. Given these recommendations our results support the need for conducting further research in this area and provide data to support the design of a definitive trial.

Acknowledgements

We acknowledge the input from our stakeholder reference and expert advisory groups; support from the Collaboration for Leadership in Applied Health Research and Care (CLAHRC) South London; Professor Charles Wolfe for his help with early drafts of this paper, and Dr Stefan Tino Kulnik for his help with final drafting.

Funding

This report presents independent research funded by the National Institute for Health Research (Research for Patient Benefit Programme; Grant Number: PB-PG-0610-22276). The views expressed in the publication are those of the authors and not necessarily those of the NHS, the National Institute for Health Research or the Department of Health.

Additional financial support for the study was provided by London (South) Comprehensive Research Network.

Contributors

All authors designed the study. FJ, RG, HG and ML performed data analysis, FJ, ML wrote initial draft and all authors commented on the manuscript.

Competing interests

FJ is the founder and director of the social enterprise Bridges self-management

Data sharing

Request for analyses of de-identified data from this trial should be directed to the corresponding author

Ethical approval

The London Surrey Borders National Research Ethics Committee gave ethical approval for this study (11/LO/1450) with local Research & Development approval granted from each of the cluster sites.

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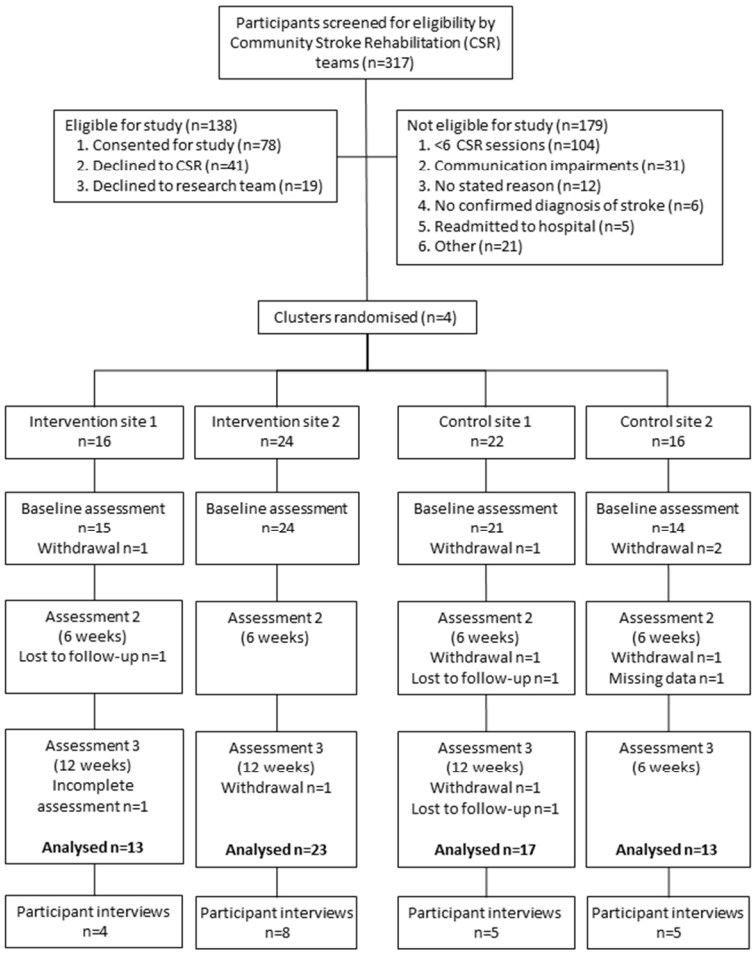

Figure 1 Study Flow Diagram
190x275mm (96 x 96 DPI)

CONSORT 2010 checklist of information to include when reporting a cluster randomised trial

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No *
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)[1,2]	See table 2	3-4
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	5-6
	2b	Specific objectives or hypotheses	Whether objectives pertain to the the cluster level, the individual participant level or both	6
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		n/a
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	7
	4b	Settings and locations where the data were collected		7, 12
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level or both	8-11
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and	Whether outcome measures pertain to the cluster level, the individual participant level or both	12-13

		when they were assessed		
	6b	Any changes to trial outcomes after the trial commenced, with reasons		n/a
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or *k*), and an indication of its uncertainty	12
	7b	When applicable, explanation of any interim analyses and stopping guidelines		n/a
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		8
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	n/a
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	8
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	8
	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete	11

			enumeration, random sampling)	
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		12
	11b	If relevant, description of the similarity of interventions		n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	13-14, 24
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		13-14
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	17
	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members	17
Recruitment	14a	Dates defining the periods of recruitment and follow-up		15
	14b	Why the trial ended or was stopped		n/a
Baseline data	15	A table showing baseline demographic and clinical	Baseline characteristics for the individual and cluster levels as	19-20

		characteristics for each group	applicable for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	17
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	20-23
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		n/a
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		14, 23-26
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms[3])		16
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		26-28
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	27-28
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		26-28
Other information				
Registration	23	Registration number and		4

		name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	n/a
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	29

** Note: page numbers optional depending on journal requirements*

Table 2: Extension of CONSORT for abstracts[1,2] to reports of cluster randomised trials

Item	Standard Checklist item	Extension for cluster trials
Title	Identification of study as randomised	**Identification of study as cluster randomised**
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	
Methods		
Participants	Eligibility criteria for participants and the settings where the data were collected	**Eligibility criteria for clusters**
Interventions	Interventions intended for each group	
Objective	Specific objective or hypothesis	**Whether objective or hypothesis pertains to the cluster level, the individual participant level or both**
Outcome	Clearly defined primary outcome for this report	**Whether the primary outcome pertains to the cluster level, the individual participant level or both**
Randomization	How participants were allocated to interventions	**How clusters were allocated to interventions**
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	
Results		
Numbers randomized	Number of participants randomized to each group	**Number of clusters randomized to each group**
Recruitment	Trial status[1]	
Numbers analysed	Number of participants analysed in each group	**Number of clusters analysed in each group**
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	**Results at the cluster or individual participant level as applicable for each primary outcome**
Harms	Important adverse events or side effects	
Conclusions	General interpretation of the results	
Trial registration	Registration number and name of trial register	
Funding	Source of funding	

[1] Relevant to Conference Abstracts

REFERENCES

1 Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, et al. CONSORT for reporting randomised trials in journal and conference abstracts. *Lancet* 2008, 371:281-283

2 Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG at al (2008) CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. *PLoS Med* 5(1): e20

3 Ioannidis JP, Evans SJ, Gotzsche PC, O'Neill RT, Altman DG, Schulz K, Moher D. Better reporting of harms in randomized trials: an extension of the CONSORT statement. *Ann Intern Med* 2004; 141(10):781-788.

TIDieR
Template for Intervention Description and Replication

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	PAGES 6, 8	
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	PAGES 6, 8-11	
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	PAGE 11	WWW. BRIDGES SELFMANAGEMENT .ORG.UK
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	PAGES 8-11	
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	PAGES 7-8	
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	PAGES 8-11	
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	PAGE 7	

	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	PAGES 24-27	
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	PAGES 9-11	
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	N/A	
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	PAGE 12	
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	PAGE 15	

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

TIDieR checklist