Virtually Home: Feasibility and pilot randomised controlled trial of a virtual reality intervention to support patient discharge after stroke

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Virtually Home: Feasibility study and pilot randomised controlled trial of a virtual reality intervention to support patient discharge after stroke

Short Title: Virtually Home: Feasibility of a virtual reality intervention to support patient discharge after stroke

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Abstract

Introduction: Virtual reality has the potential to assist occupational therapists in preparing patients for discharge by facilitating discussions and providing education about relevant practical issues and safety concerns. This study aimed to explore the feasibility of using a virtual reality intervention to support patient discharge after stroke and pilot its use.

Method: Practical aspects of delivering a virtual reality intervention prior to discharge were explored by means of a non-randomised feasibility study and a subsequent pilot randomised controlled trial. Factors considered included eligibility, recruitment, intervention delivery, attrition, and suitability of outcome measures. Outcome measures included standardised assessments of stroke severity, mobility, health-related quality of life, functional ability, satisfaction with services, and concerns about falling.

Results: Thirty-three participants were recruited in total: 17 to the feasibility study and 16 to the pilot trial. At one-month follow-up, 14 participants (82%) were re-assessed in the feasibility and 12 (75%) in the pilot. The main difficulties encountered related to recruitment, particularly regarding post-stroke cognitive impairments, the presence of mild deficits, or illness.

Conclusion: It was feasible to recruit and retain participants, deliver the intervention and collect outcome measures, despite slow recruitment rates. These findings could inform the design of a definitive trial.

Keywords: Occupational therapy, virtual reality, stroke, rehabilitation, discharge planning, home visits

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Introduction

Pre-discharge home assessment visits ('home visits') are an established part of occupational therapy (OT) practice across UK stroke services. They are defined by the Royal College of Occupational Therapists as:

"… a visit to the home of a hospital in-patient which involves an occupational therapist/s in accompanying the consumer to assess his/her ability to function independently within the home environment" (p1). By comparison, 'access visits' can be carried out, whereby a therapist visits the patient's home without the patient being present, in order to assess factors such as space requirements for assistive equipment and access issues (Drummond et al., 2012).

However, there is limited evidence for the effectiveness of either of these interventions (Barras, 2005; Chibnall, 2011; Drummond et al., 2013; Lannin et al., 2007; Lockwood et al., 2015), although there is promise from the evaluation of broader home modification interventions for falls prevention and improving functional outcomes among older adults (Clemson et al., 2008; Stark et al, 2017). Differences in local hospital policies and availability of resources mean that there is also considerable variation in the level of pre-discharge assessment and intervention that patients currently receive (Drummond et al., 2012; Whitehead et al., 2014). For the majority of patients, discharge planning is largely managed in the hospital setting via ward-based assessments, information provision, and discussions with the therapy team.

Exploration of new approaches to supplement the provision of information by therapists has the potential to result in an enhanced, as well as more standardised, level of pre-discharge intervention delivered in the hospital setting. One such new approach that could facilitate discussions about the patient's home environment is the use of low-cost, non-immersive virtual reality (VR). To date, there have been a small number of studies examining VR in discharge planning, in falls prevention in older adult care, and in informing the need for home modifications (e.g. Atwal et al., 2013, 2014; Bianco et al, 2016). A recent preliminary study (Threapleton et al., 2016) explored the potential suitability of a VR application that represented a range of 'generic' home environments, each containing typical rooms, household furniture, fittings, and personal possessions. The findings indicated that both therapists and patients perceived the VR application to have the potential to support patients in preparing for discharge after stroke. This initial research directed the development of the 'Virtual Home' (VH) application used in the present study.

Given current widespread resource constraints (Whitehead et al., 2014), this VH application could offer an affordable, accessible, and time-efficient approach to facilitating discharge after stroke. This may help patients to identify relevant safety concerns, explore any anxieties, and identify activities that might prove difficult to manage in the home environment. It also could aid therapists in encouraging realistic expectations and discussing management strategies. Overall, this application could enable patients to feel supported and informed about their discharge, and facilitate a positive transition home (Ellis-Hill et al., 2009; Mountain and Pighills, 2003).

However, while preliminary studies suggest that VR may be a suitable tool to support discharge planning (e.g. Atwal et al., 2013, 2014; Threapleton et al. 2016), there have been no trials to date to directly examine this. As the VH application is a novel approach, with no direct comparators available in the literature, the aim of the current research was firstly to explore the feasibility of using the VH as an intervention to support patient discharge from hospital after stroke, and secondly to test its use in a pilot randomised controlled trial. Thus, the aims of the study were to assess the practical factors associated with delivering the intervention, including recruitment and retention of participants, patient eligibility criteria, randomisation, viability of scheduling and delivering the intervention prior to discharge, and suitability of outcome measures, and to collect pilot data to inform a definitive trial.

Method

Ethical Considerations

Ethical approval was obtained and all participants provided written informed consent and were free to withdraw at any stage. All data collected up to the point of withdrawal were included in the analyses.

i) Feasibility Study

Design

This was a two-centre non-randomised feasibility study. All participants received the VH intervention prior to discharge. This took place during a supplementary session with an Occupational Therapist in addition to usual routine care. Usual care included a home and/or access visit if required. Participant follow-up was at one month after discharge.

Participants

Since this was a feasibility study, no formal sample size calculation was required. The aim was to recruit approximately 20 participants. The target was pragmatic on what would provide sufficient data for an exploratory study within the available resources and timescale.

Participant recruitment took place at the inpatient stroke wards of two regional hospitals. Eligible participants were aged 18 years or over with a confirmed diagnosis of stroke. Patients were excluded if they: were unable to follow a two-stage command; were non-English speaking or unable to communicate verbally; had epilepsy triggered by screen images; lacked capacity to consent; had severe visual impairments; had been admitted from or were being discharged to a care home; had a poor prognosis or were receiving palliative/end-of-life care. Poor prognosis was defined as being medically unstable and/or not currently considered appropriate for discharge home (this was determined by review of the medical notes and/or discussion with the multi-disciplinary team).

There were no restrictions placed on the time between stroke onset and recruitment. However, a minimum of 24 hours' notice was required between consent and the patient's

estimated discharge date, in order to collect baseline outcome measures and deliver the intervention prior to discharge.

Procedure

Participant recruitment was facilitated by the National Institute of Health Research (NIHR) Clinical Research Network (CRN) which provides an infrastructure to support the delivery of research within the NHS across England. Clinical Trial Nurses (CTN) undertook patient eligibility screening and obtained informed consent. Demographic information, medical details, and baseline outcome measures were subsequently collected by a member of the research team. Assessments included standardised measures of the following: stroke severity, using the Oxfordshire Community Stroke Project Classification (Bamford et al., 1991) and National Institute of Health Stroke Scale (NIHSS); disability, using the Modified Rankin Scale (Van Swieten et al., 1998) and Barthel Index (Collin et al., 1988); mobility, using the Rivermead Mobility Index (Collen et al., 1991); health-related quality of life, using the EuroQol EQ-5D-5L (EuroQol Group, 1990); and functional ability, using the Nottingham Extended Activities of Daily Living Scale (Nouri & Lincoln, 1987). A measure of satisfaction was obtained using the Patient Satisfaction Index (Lincoln, et al., 2003), whereby participants rated their level of satisfaction across six items: 1) knowledge of what a stroke is; 2) knowledge about their expected recovery; 3) information received about reducing the risk of future strokes; 4) information received about community services; 5) practical help received (such as assistive equipment); 6) their overall satisfaction with hospital care and/or community services. A four-

point Likert scale was used to rate satisfaction levels for each item, ranging from 0 ('I am very dissatisfied') to 3 ('I am very satisfied'). Participants did not rate items 3-5 if they had not received the relevant information.

Following baseline assessments, all participants took part in a single intervention session consisting of a 'tour' of the VH delivered by an occupational therapist. The VH represents a generic home environment with a choice of two alternative virtual living arrangements: either a house or a level bungalow. In addition to standard household items, the VH included examples of access and layout difficulties (e.g. steps/stairs, narrow hallways, uneven ground), and various safety risks (e.g. trip hazards such as rugs, 'clutter' and trailing electrical leads). There were also customisable features, including the options to:

- add items of assistive equipment (including internal/external grab rails, temporary ramp, key safe, perching stool, kitchen trolley, pendant alarm, commode, Oxford Mini Hoist, toilet frame, bath board).
- alter the bathroom layout to show: bath only, shower-over-bath, shower cubicle, or wet room.
- depict 'downstairs-only' living arrangements, if required (in the 'house' scenario only, with a choice of a standard or hospital bed).

The VH was developed using Unity® software (Unity Technologies, San Francisco, California) and shown on a 10.5" touchscreen tablet, which was easily portable, could be stored securely, and readily sanitised for infection control purposes. Navigation was via

touchscreen controls; to aid navigation, a 'map' function was included, whereby the user could select a room or area to move to without having to 'walk' to it. (See online-only supplementary figures for examples.)

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Three therapists from the sites multi-disciplinary teams were involved in delivering the intervention. Each had received training over two sessions, as well as further individual practice. Following prior discussions with the therapists, a formal structured protocol to guide the intervention was not developed, as they preferred to use the intervention in consideration of individual patient need. However, the key objectives of the intervention were reinforced as part of the training: namely, to prompt patients to think about their own home in order to identify and address relevant issues and to guide discussions about their transition home.

As part of the intervention delivery, identification of potential safety risks and/or practical difficulties in the management of activities of daily living was encouraged, and possible coping strategies discussed. Examples of discussion topics included: identifying and removing potential trip hazards, managing access, stair mobility, adapting to downstairs living, bathing, toileting, and kitchen-based activities. Discussions concerning the use of assistive equipment occurred where appropriate, for example, showing items of assistive equipment and how they are fitted, used, and stored safely at home. Patients were prompted to describe the layout of their own home in relation to the VH throughout, ensuring that the most appropriate configurations and options were selected by the therapist. The therapist's prior knowledge of the patient's living situation was also taken into account in configuring the VH; therapy teams

routinely collect this information during initial interviews after admission, to guide subsequent discharge planning.

The intervention was scheduled according to the participant's estimated discharge date, as well as staff availability. A member of the research team attended each intervention session in order to record field notes and assist with any technical issues. Family members were invited to attend if they wished. All sessions were audio recorded.

Follow-up took place at the participant's home one-month after discharge. Assessments were repeated as at baseline. Additional information was collected on the participant's home environment, and whether a home visit or access visit had also been carried out. Safety outcomes, including the number of falls and readmissions to hospital since discharge, were also recorded.

At the end of the recruitment phase, the therapists were invited to take part individually in a semi-structured interview to provide feedback on their overall perceptions of the VH application. The interviews were audio recorded and transcribed verbatim.

Results

Data Analysis

Data analysis focused on feasibility findings and included recruitment and retention of participants, appropriate inclusion and exclusion criteria, viability of scheduling and delivering the intervention prior to discharge, and suitability of outcome measures.

Data were analysed using IBM SPSS Statistics, Version 22.0 (IBM Corporation, Armonk, NY, USA) and descriptive statistics were used to analyse feasibility findings.

As the data for some outcome measures were not normally distributed, and included ordinal data, medians and interquartile ranges were calculated. Qualitative interview data were analysed by thematic analysis (Braun and Clarke, 2006).

Recruitment and Retention

Recruitment commenced in May 2015 and ended in October 2015. Recruitment figures and the flow of participants through the study are shown in Figure 1.

A total of 1207 patients were assessed for eligibility across the two sites, of whom 34 met the inclusion criteria and 1173 did not (reasons for ineligibility are outlined in Figure 1). Of the 34 patients meeting the criteria, 17 provided informed consent and 17 declined to participate. Although recruitment figures fell below the original recruitment target of 20, the consent rate was 50% of those eligible. Further to the specified eligibility criteria, emerging reasons regarding why patients are not approached to participate were also identified (Figure 1).

[*Insert Figure 1 here*]

Of the 17 participants recruited, 16 (94%) completed baseline assessments and received the intervention; one participant was subsequently discharged the day after joining the study before any study procedures could be completed. One month follow-up assessments were completed with 14 (82%) participants; one withdrew having declined a follow-up visit, and one was re-admitted to hospital and was no longer able to take part. Attrition rates were therefore minimal.

Demographic details of participants are shown in Table 1. Prior to stroke onset, the majority of participants (n=13, 81%) had been living independently without formal support or care; two (13%) had some items of assistive equipment already in place at home (e.g. stair lift, grab rails), and one (6%) lived in a warden-aided ground floor flat. The majority of participants lived with either a partner/spouse, or with other family members, and in a house with stairs. Following hospital discharge, six participants (38%) returned home to downstairs living arrangements, and one (6%) who lived in shared housing accommodation was discharged to a care home due to issues with installing assistive equipment at home. Ten participants (63%) reported having some previous experience in the use of computers or touchscreen devices.

[Insert Table 1]

Viability of Scheduling and Delivering the VH Intervention

Scheduling the intervention was largely determined by therapists' availability and the estimated discharge date from hospital. On average there were five working days (median=5; IQR=2-10) between consent and their estimated discharge date, during which the intervention

session could be delivered. The median length of time prior to the participant's actual discharge date that the intervention was conducted was four days (IQR=1-10). The median length of the intervention was 24 minutes (IQR=14-34). In addition to the VH intervention, eight participants (50%) received an access visit and two (12%) received a home visit prior to discharge.

Suitability of Outcome Measures

Details of participant outcomes at baseline and one month follow-up are shown in Table 2. Improvements were generally shown on all measures, except for self-rated health status (EQ-5D-5L Visual Analogue Scale). Ceiling effects were observed at follow-up for one participant on the Rivermead Mobility Index and for seven participants on the Barthel Index (i.e. the maximum score was reached, and therefore no further improvements could be shown). Overall, the Participant Satisfaction Index indicated that participants were very satisfied with hospital and/or community services and with the practical help received.

Regarding safety measures, four participants (29%) reported at least one minor fall between discharge and follow-up (mean number of falls for those reporting a fall = 2.5 (SD=1; range = 2-4). Three participants (21%) had been readmitted to hospital during the one month follow-up period. Of these, two were readmitted for non-stroke related reasons and one was readmitted with a further stroke.

One month follow-up assessments were completed on average within one week of their scheduled date (median=6.5 days; IQR=3-9). Where follow-up assessments were completed

later, this was generally due to difficulties in contacting the participant or scheduling visits, readmissions to hospital, or family members requesting to be present.

[Insert Table 2]

Feasibility Findings

It was feasible to conduct a non-randomised study of the VH intervention and to recruit participants, deliver the intervention prior to discharge, and retain participants for follow-up. However, some difficulties were encountered with recruitment rates; it took six months to recruit 17 participants. Patient exclusion was for a variety of reasons; a high proportion of patients were discharged prior to approach, however this was predominately those with very short hospital stays who required little therapy intervention. However, there were also instances in which participation was affected by staff availability to undertake patient screening (for example, due to periods of annual leave or training). Recruitment was also affected by high numbers of non-stroke admissions (or those with a TIA diagnosis), as well as high numbers of patients lacking capacity to consent due to cognitive impairment, patients with a poor prognosis, and those receiving palliative care or being discharged to a residential home. Further eligibility criteria were also identified during the feasibility study. These included having very mild deficits, living out of catchment area (such that follow-up visits would not be possible), having significant co-morbidities, having low mood (such that the care team felt that the intervention was not appropriate), and being identified by clinical staff as high risk for a follow-up visit by a single assessor (e.g. history of aggressive behaviour).

The majority of those recruited received the intervention. Only one participant did not receive the intervention due to being discharged before their estimated discharge date. Overall it was possible to liaise with therapists and deliver the intervention prior to discharge. Only two participants (13%) had a family member present, which may have been due to sessions often being scheduled at short notice to fit around therapists' availability. Some patients were recruited very close to their estimated discharge date, despite the average total length of stay being 30 days. In part, this was due to discharge planning typically occurring late in the patient stay, but also due to staff availability for screening and identifying potential participants ahead of discharge.

Feedback from the therapists indicated that the touchscreen tablet was suitable, and no major technical difficulties were encountered. Feedback also identified suggestions for further improvements to the VH content, which were implemented after the recruitment phase had been completed. These included general usability improvements, such as better accessibility of option menus and navigation controls, more household items, the addition of pet paraphernalia (e.g. bowls, litter tray), and further items of assistive equipment, including patient transfer aids, toilet seat raisers and frames, and a portable table.

Good follow-up rates (82%) for the completion of outcome measures at one month were also achieved. Only one participant declined to participate further following discharge. Thus, overall acceptability of the research procedures and intervention was demonstrated. Outcome measures generally showed improvements between baseline and follow-up, although

participants tended to rate their health status (EQ-5D visual analogue scale) lower at follow-up than at baseline. Ceiling effects were observed for the Barthel Index and Rivermead Mobility Index, and there was very little variation in scores across the Participant Satisfaction Index.

ii) Pilot RCT

The aim of the second phase was to further explore the delivery of the VH and to collect data to inform a definitive trial.

Design

This was a single-centre randomised pilot trial. Participant recruitment took place at the inpatient stroke wards of a regional hospital, which had not participated in the feasibility study. Participants were randomised to receive either the VH intervention, as in the feasibility study, or usual care alone (control). Participant follow up was at one week and one month post discharge.

Participants

The previous eligibility criteria were used; however, based on the feasibility findings, the following additions were made: very mild deficits, living out of catchment area, having multiple comorbidities, having low mood, and being considered high risk for a lone researcher visit. The aim was to randomise approximately 16 participants. This target was again pragmatic based on recruitment rates achieved within the feasibility study, discussions with staff regarding the potential number of participants available and the given timeframe at the site.

Procedure

Outcome assessments were as for the feasibility study, except for removing the Patient Satisfaction Index (Lincoln, et al., 2003) as responses tended to be very similar across all items. The Falls Efficacy Scale-International (FES-I) (Yardley et al., 2005) was added. This scale measures the level of concern about the possibility of falling across 16 everyday activities (such as getting dressed), on a four-point Likert scale from 1 ('not at all concerned') to 4 ('very concerned').

Participants were recruited by the local CTN. Following the completion of baseline assessments, participants were randomly allocated to either the intervention or control group. Randomisation was managed by an independent research administrator who held a web-generated list for a two group randomisation sequence with a 1:1 allocation. Sealed opaque envelopes were pre-prepared and labelled with specific participant identification numbers. Group allocation was only revealed after completion of baseline assessments.

As described in the feasibility study, participants in the intervention group took part in a single VH session prior to hospital discharge. The intervention was led by one of two occupational therapists who had received prior training as previously outlined. Participants in the control group received usual care only.

All participants were followed up at home one week and one month after discharge by a blinded assessor. The assessments completed at baseline were repeated, and additional information was collected as previously described, including the incidence of falls and hospital

readmissions. As with the feasibility study, the therapists were invited to take part in a semi-structured interview to provide feedback on their perceptions of the VH application. These interviews were audio recorded and transcribed verbatim.

Results

Data Analysis

Data were analysed as described for the feasibility study.

Recruitment and Retention

Recruitment took place between March and September 2016. Recruitment figures and the flow of participants through the study are shown in Figure 2.

A total of 183 patients were assessed for eligibility, of whom 22 met the inclusion criteria and 161 did not (reasons for ineligibility are outlined in Figure 2). Of the 22 patients who met the criteria, 16 (73% of those eligible) provided informed consent.

[*Insert Figure 2 here*]

Participant attrition is shown in Figure 2. Of the 16 participants recruited, all completed baseline measures and were randomised prior to hospital discharge. Eight were randomised to the intervention and eight to the control. Overall, one week follow-up assessments were completed with 14 (88%) participants; two could not be contacted following discharge. One month follow-up assessments were completed with 12 (75%) participants; one had died, and

one was re-admitted to hospital and was too unwell. Attrition was thus equal between groups (n=2 in each).

Demographic details are shown in Table 1. Prior to stroke onset, all participants were living independently without the need for formal support, although three (19%) had informal care provided by their spouse or family. Four participants (25%) had some items of assistive equipment already in place (e.g. shower seat, grab rails). The majority of participants lived with either a partner/spouse and in a house with stairs (or had stair access). Following hospital discharge, three (19%) participants returned to downstairs living; one from the control group and two from the intervention group. Two participants from the intervention group went to live with other family members on discharge. Seven participants (44%) reported having some previous experience in using computers or touchscreen devices.

Viability of Scheduling and Delivering the VH Intervention

All participants randomised to the intervention (n=8) received the intervention as planned. As with the feasibility study, scheduling of the intervention was largely determined by therapists' availability. On average there were four working days (median=4; IQR=2-5) between consent and the estimated discharge date during which the intervention session could be delivered. The average length of time prior to the participant's actual discharge date that the intervention was conducted was three days (median=3; IQR=1-4). The median length of the intervention was 27 minutes (IQR=22-31).

In addition to the VH intervention, three participants (38%) from the intervention group received an access visit, and two (25%) received a home visit prior to discharge; two participants (25%) from the control group also received a home visit.

Suitability of Outcome Measures

Details of participant outcomes at baseline, one week and one month follow-up are shown in Table 3. There were some differences observed between the groups. Scores on the modified Rankin were comparable at baseline across both groups, with the intervention group showing greater improvement at one-month follow-up. The Barthel Index generally showed the greatest variation, with the largest improvement observed from baseline to one-month follow-up for the intervention group. This pattern was also observed for the Rivermead Mobility Index and NEADL. All participants improved on the FES-I, with the largest improvement for the intervention group at one-week; both groups were equal at one-month follow-up. The EQ-5D-5L Index and VAS showed a range and variation of scores across all time points for both groups. For the EQ-5D-5L, both groups showed less favourable scores at one-week follow-up; while the intervention group improved in line with the baseline score at one-month, the control group scores remained less favourable than at baseline. With the VAS, although the intervention group scored higher at baseline, the control group showed the most improvement by one-month follow-up. While it is not appropriate to analyse these differences statistically, the results suggest that these measures have the potential to show group differences in a definitive trial.

In relation to safety measures, two participants from each group (12.5%) reported one minor fall between discharge and follow-up, but neither required treatment. Two participants (25%) from the intervention group were readmitted to hospital between the one week and one month follow-up time points. Of these, one was readmitted for non-stroke related reasons, and one was readmitted with a further stroke and subsequently died.

On average, follow-up assessments were completed within five days of their scheduled date for both the one week (n=14; median=5 days; IQR=1-7) and one month (n=12; median=4 days; IQR=1-7.5) time points. Where follow-up assessments were completed later than this, the reasons were similar to those in the feasibility study, including difficulties in contacting the participant, conflicts in appointment scheduling with other services, and family members requesting to be present at the visit.

[Insert Table 3]

Discussion and Implications

Overall, findings from the feasibility study and pilot RCT show that it was feasible to recruit, randomise, and retain participants for follow-up assessments, and to deliver the intervention. Intervention delivery rates were high, and all participants randomised to the intervention group in the pilot trial received the intervention as planned.

Consent rates were acceptable for those who were approached to participate (pilot 73%; feasibility 50%). Attrition rates were also satisfactory, with 82% of participants in the feasibility study and 75% in the pilot study completing final follow-up assessments. Across both phases,

follow-up assessments were typically completed on time or within one week of their scheduled date. On average, the intervention took 24 minutes to deliver in the feasibility study and 27 minutes in the pilot. The time taken to set up the intervention was minimal due to the use of the portable touchscreen tablet. The time required to deliver the intervention could, therefore, be considered broadly achievable in current OT practice.

Recruitment rates in the feasibility study were generally slow across the two sites, with the result that recruitment targets were not reached. Whilst this was due largely to local site issues, it may also be indicative of the timescales needed to recruit participants to a larger trial. By comparison, recruitment targets were met in the pilot trial at a single site, in a similar timeframe to the feasibility study, suggesting potential for improvements in recruitment rates. The main reasons for exclusion in both studies were the presence of mild deficits, significant cognitive impairments, and illness. Patient discharge prior to approach was less problematic in the pilot than the feasibility study. Over the course of the feasibility study, additional eligibility criteria were established, which informed the pilot RCT.

There were some difficulties encountered in scheduling the intervention prior to discharge. In both studies, some patients were recruited very close to their estimated discharge date, suggesting that opportunities were missed to recruit them earlier. In general, therapists were limited in terms of when they could schedule and deliver the intervention, since this research was undertaken in addition to their usual workload. This lack of flexibility also meant that it was difficult to include family members in intervention sessions. It is possible that, if the

intervention were delivered as part of routine care, such difficulties may be alleviated. However, strategies to identify suitable patients earlier within their hospital stay would be required for future research.

This feasibility study and pilot RCT represent the first direct use of the VH application to facilitate and support discussions with patients after stroke concerning their discharge home. This has provided preparatory data for future research. Feedback from the therapists indicated that the intervention was acceptable to them, and identified further potential improvements for the content of the application. Although this was not a powered study, some outcome measures indicated the potential to show sensitivity to change. Within the pilot RCT, favourable trends were observed across outcome measures for the intervention group. However, these observations should be interpreted with caution. It is worth noting that participant allocation to the VR intervention could not be concealed from the multi–disciplinary teams. Consequently, although clinical decisions regarding usual care were independent to the study intervention, this could have had an underlying influence on home visits rates at the sites.

Whilst patients lacking capacity to consent and/or those with significant aphasia were excluded, it may be possible to explore the use of the VH intervention for these patients in future research through, for example, greater involvement of carers to facilitate discussions. Indeed, more widely, it may be beneficial to arrange sessions so that a carer could be present. Further evaluation of the patient's physical environment, and the provision of assistive

equipment in relation to recommendations made during the intervention, are also important factors to address in future research. There may be scope in future to use the VH in conjunction with photographs and/or videos of the patient's home in order to support the clinical recommendations made following the intervention (Clifford and Heward, 2015). Finally, cost implications and/or potential savings were not examined within the current studies, but would merit consideration in future research.

Conclusion

This research was novel in directly exploring the use of VR as an intervention to support discharge after stroke. Overall findings suggest that the intervention is feasible to deliver as part of the discharge process and warrants future evaluation. Further research is important for OT practice as this intervention has the potential to form the basis of a standardised and accessible approach to support patient discharge after stroke. In consideration of the feasibility and pilot findings, the next stage of the research should be a multi-centre pilot RCT to explore the identified issues ahead of a definitive trial.

Key Findings

- The VH was feasible to deliver as part of the discharge process after stroke.
- The main difficulties related to recruitment and intervention scheduling.
- Further evaluation is feasible and warranted.

What the study has added

This was the first feasibility study and pilot RCT to explore the use of virtual reality directly as an intervention to support patient discharge after stroke.

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Research ethics

Ethical approval was obtained from the Research Ethics Committee (NRES Committee East Midlands – Leicester; REC Ref: 13/EM/0397; November 2013). All participants provided written informed consent and were free to withdraw at any stage.

Declaration of conflicting interests

The Authors confirm that there is no conflict of interest.

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Table 1: Feasibility Study & Pilot Trial Demographics

Characteristic	Feasibility Study	Pilot Trial	
	(n=16) n (%)	Intervention (n =8) n (%)	Control (n =8) n (%)
Gender:			
Male	11 (69%)	2 (25%)	5 (25%)
Female	5 (31%)	6 (75%)	3 (19%)
Age:			
Mean (SD)	63 years (SD 13.34)	72 years (SD 21.08))	70 years (SD 12.6)
Range	43-84 years	38 – 90 years	46 – 86 years
House Type:			
House (with stairs)	13 (81%)	3 (37.5%)	5 (62.5%)
Bungalow/flat	3 (19%)	4 (50%)	3 (37.5%)
Flat with stair access	0 (0%)	1 (12.5)	0 (0%)
Living Arrangements:			
Lives with partner/spouse	6 (37.5%)	3 (37.5%)	6 (75%)
Lives alone	6 (37.5%)	4 (50%)	2 (25%)
Lives with other family	3 (19%)	1 (12.5%)	0 (0%)
House Share*	1 (6%)	0 (0%)	0 (0%)
Length of Hospital Stay:			
Median (IQR)	30 days (20-54)	23 days (18-31)	17 days (7-30)
NIHSS Stroke Severity:			
Minor Stroke (1-4)	5 (31.25%)	2 (25%)	1 (12.5%)
Moderate Stroke (5-15)	9 (56.25%)	3 (37.5%)	7 (87.5%)
Moderate to Severe Stroke (16-20)	1 (6.25%)	2 (25%)	0 (0%)
Severe Stroke (21-42)	0 (0%)	0 (0%)	0 (0%)
Missing	1 (6 6.25%)	1 (12.5%)	0 (0%)
Bamford Classification			
POC	7 (44%)	1 (12.5%)	1 (12.5%)
LAC	6 (38%)	3 (37.5%)	3 (37.5%)
PAC	2 (12%)	1 (12.5%)	2 (25%)
TAC	1 (6%)	3 (37.5%)	1 (12.5%)
Missing	0 (0%)	0 (0%)	1 (12.5%)
Previous Stroke - Yes	2 (12.5%)	1 (12.5%)	1 (12.5%)

*Participant rented a room in a shared house

Table 2: Feasibility Outcome Measures

Measure	Baseline (n=16) Median (IQR)	Follow-up at 1-Month (n=14) Median (IQR)
Modified Rankin*	3.5 (3-4)	3 (2.75-3.25)
Barthel Index**	14 (9.25-17.00)	19 (12.50-20.00)
Rivermead Mobility Index**	6.5 (3.25-8.00)	11.5 (6.75-13.00)
EQ-5D-5L:		
Index Value**	0.37 (0.14-0.55)	0.59 (0.42-0.69)
Visual Analogue Scale**	62.5 (47.75-75.00)	55 (50.00 – 71.25)
NEADL**	9.5 (8.00-11.75)	22.5 (12.00-31.25)
Patient Satisfaction with:		
Knowledge of Stroke**	2 (2-3) (n=16)	2 (2-3) (n=14)
Recovery**	2 (1-3) (n=16)	2 (1-3) (n=14)
Reducing the Risk**	2.5 (1.25-3) (n=4)	3 (2-3) (n=5)
Community Services**	3 (2-3) (n=11)	3 (1.75-3) (n=11)
Practical Help**	3 (2-3) (n=10)	3 (2.5-3) (n=13)
Overall Satisfaction**	3 (2.25-3) (n=16)	3 (3-3) (n=14)

(*lower score indicates better outcome; **higher score indicates better outcome)

Table 3: Pilot Outcome Measures

Measure	Baseline		Follow-up at 1-Week		Follow-up at 1-Month	
	Intervention (n=8) Median (IQR)	Control Group (n=8) Median (IQR)	Intervention (n=8) Median (IQR)	Control Group (n=6) Median (IQR)	Intervention (n=6) Median (IQR)	Control Group (n=6) Median (IQR)
Modified Rankin*	4 (3-4)	4 (3-4)	3.5 (3-4)	3.5 (2.25-4)	3 (2.75-3.25)	3.5 (1.75-4)
Barthel Index**	12 (9-14)	14.5 (10.5-18.25)	13.5 (8.5-15)	13.5 (9.25-17.75)	17.5 (11-18.5)	15 (9.5-19.25)
Rivermead Mobility Index**	5.5 (3-8.75)	7 (2.75-10.75)	7.5 (3.25-9.75)	7.5 (4.25-12.5)	12 (5.75-12.25)	8 (5.75-12.5)
EQ-5D-5L: Index Value** Visual Analogue Scale**	 0.58 (0.39-0.70) 67.5 (50-82.25)	 0.48 (0.17-0.72) 48.5 (28.75-82.5)	 0.41 (0.27-0.56) 60 (40-75)	 0.26 (0.05-.82) 77.5 (33.75-81.25)	 0.59 (0.08-0.69) 62.5 (60-72.5)	 0.40 (0.18-0.91) 72.5 (26.25-88.75)
NEADL**	11 (6.25-15.25)	10 (7.25-17.25)	12.5 (8-18.25)	11.5 (9.25-30.25)	25 (13.25-43)	13 (11.25-32.25)
Falls Efficacy Scale-International**	29.5 (20-42.25)	27.5 (18-43)	47.5 (28.75-53.75)	33.5 (23-63.25)	37 (31.25-55.5)	37 (21.5-53.25)

(*lower score indicates better outcome; **higher score indicates better outcome)

Figure 1: Feasibility CONSORT Diagram

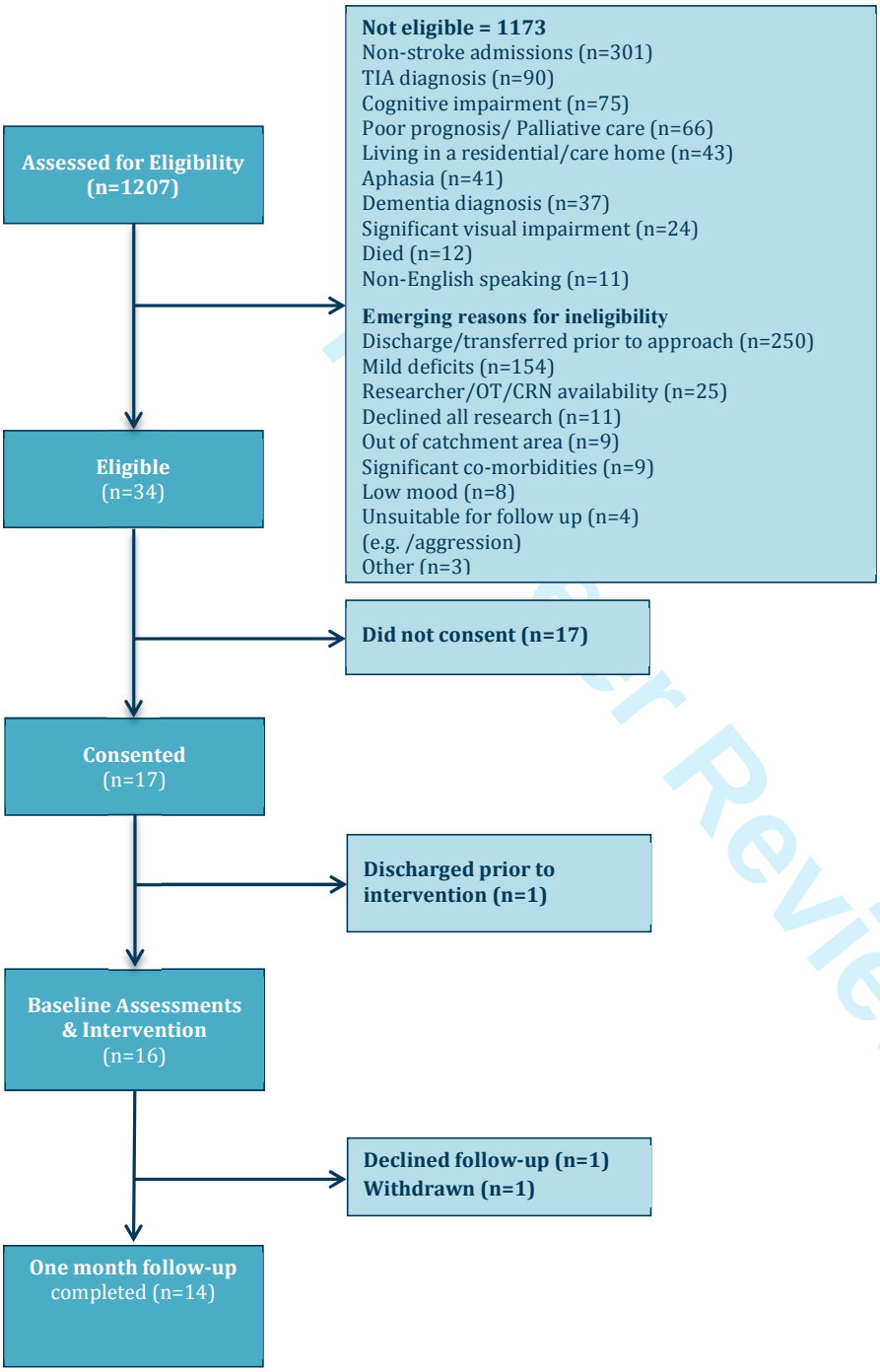
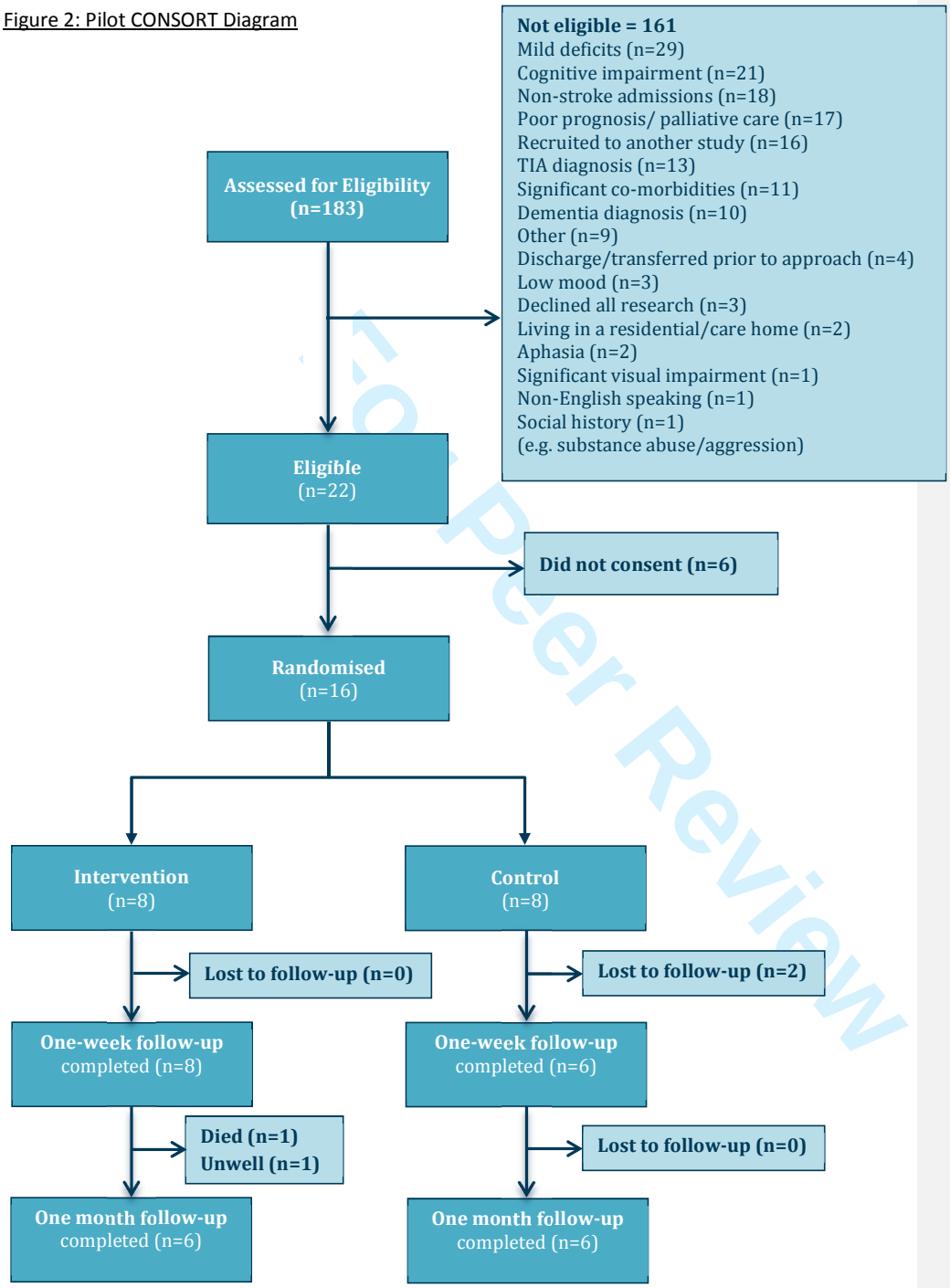


Figure 2: Pilot CONSORT Diagram



136x84mm (220 x 220 DPI)

114x71mm (220 x 220 DPI)

105x65mm (220 x 220 DPI)

105x65mm (220 x 220 DPI)