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Virtual Reality for Fear of Falling in Older People

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BSc (Hons), MSc, PgCert

Submitted in partial fulfilment of the requirements for the
Degree of Doctorate in Clinical Psychology (D.Clin.Psy)

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Augmenting psychological treatment for fear of falling using Virtual Reality: A feasibility study in older adults

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Luke Barracliffe

Foreword

The original study involved testing the Virtual Reality Fear of Falling intervention in-person with older people, allowing use of measures in addition to those eventually used, such a sense of immersion and presence. Due to the COVID-19 pandemic, which began part way through this study's development, this became unfeasible. This was due to government lockdown restrictions and as this research involved at-risk populations. The primary researcher made drastic changes and adaptations, rendering it entirely remote. This had implications for recruitment, materials, costs and aims. This also slowed the ethics process.

Due to these necessary adaptations, this thesis is being submitted under 'Contingency Plan 2'

CHAPTER 1: Systematic Review

Exploring the use of Virtual Reality in Fear of Falling in Older Adults:

A Systematic Review

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Abstract

Background:

Falls in older adults reduce quality of life for victims and are expensive to health services. Falls risk is increased by Fear of Falling (FoF). Virtual reality (VR) exposure treatments can improve FoF and potentially save labour and costs. Past reviews have primarily focused on video games and less immersive VR.

Aims:

Examine the ways in which VR is used in relation to FoF in older people, review how outcomes relevant to FoF are measured, explore acceptability and report any barriers to VR implementation.

Methods:

Four databases were searched for studies which met inclusion criteria. Data from the studies were extracted, their quality assessed and results synthesised.

Results:

Seven studies were included. There was large variation in VR content, exposure length and sample characteristics. Evidence is limited regarding longevity of effects. Method of FoF measurement was varied, often being a secondary outcome to balance- though VR was well accepted with generally good adherence.

Conclusion:

VR via HMDs is accepted by older adults and beneficial for FoF in the short term. Given the need for reduced labour costs, VR could be a step closer to successful FoF treatment.

Keywords: Virtual Reality; Fear; Falling; Review; Anxiety.

1. Introduction & Theory

1.1 Background

The purpose of this review is to summarise and critically analyse the evidence on the use of Virtual Reality (VR) for Fear of Falling (FoF) in older adults. An established definition of FoF is a reduced confidence in balance abilities (Maki et al., 1991) resulting in avoidance of activities that people can still physically perform (Tinetti & Powell, 1993). It can develop independently of previous falls (Public Health England [PHE], 2017). A significant number of older adults (≥ 65 years) experience falls and the risk increases with age (National Institute for Health and Care Excellence [NICE], 2013). Inevitably, this incurs great cost to UK public health services, including in Scotland (Craig et al., 2013; McGinley et al., 2020; PHE, 2017). Annually, emergency hospital admissions cost the NHS up to £2-billion and social care following fall-related fractures cost £1-billion (NICE, 2018; PHE, 2017); associated annual costs in Scotland are over £470-million (Craig et al., 2013). This is reflected internationally, with yearly costs in California USA alone being over £3-billion (Haddad et al., 2019). Consequences for individuals can include reduced social interaction, lower quality of life (QoL) and even premature death (Arfken et al., 1994; Fuller, 2000; Jung et al., 2009).

Some exercise-based interventions have attempted to target the balance aspect of FoF, with low to moderate benefits (Levy et al., 2016; Rand et al., 2011). Meta-analytic data suggest these may be effective in improving FoF, however mean effect-sizes were small (*Cohen's d* = 0.2) and most of the studies reviewed found treatment was ineffective (Jung et al., 2009). Such interventions also neglect the cognitive elements of FoF; since FoF can be considered an anxiety disorder involving complex psychological processes, it makes sense to address this in interventions too (Levy et al., 2016; Young & Mark-Williams, 2015).

Additionally, there is also a need for reduced costs and labour in such psychological interventions, which can be assisted by semi-automated technology; this could mean one clinician could provide therapy for multiple people engaging in the automated technology for example, thus saving labour costs (Freeman et al., 2018).

Some studies have used traditional video games to address FoF (Jorgensen et al., 2013; Pietrzak et al., 2014; Seamon et al., 2017). Video games for the purpose of such treatment are known as 'serious games', which are a type of video game with purposes beyond just entertainment, such as treatment and education. Commercial systems can be utilised for serious gaming, including the Nintendo Wii. Some studies incorporated commercially available fitness-based serious games, including dancing, to treat FoF (Rodrigues et al., 2018). However, their results mimic those of the exercise-based studies. Specifically, a review found little evidence that balance-training serious games prevent falls or reduce FoF; they reported that many games are distracting to older people, given they were not designed to target FoF (Pietrzak et al., 2014).

Psychological exposure via Virtual Reality (VR) is a more modern approach to addressing FoF which could meet the need to reduce labour costs, as well as targeting cognitive aspects of FoF. It is also relatively affordable considering it can be used long-term, with the recent 'Oculus Quest 2' VR system retailing at £200-300. VR is an interactive computer simulation in which users' actions are sensed and fed back to one or multiple senses (e.g. visual or haptic); they then become immersed in the virtual environment (Mihelj et al., 2014). It usually involves users wearing goggles or a helmet ('Head Mounted Device' [HMD]) through which they view virtual worlds, which tracks where they look. They also use hand-held controllers which track their hand-location, allowing them to interact with virtual objects. VR therapy for FoF could occur in a clinical or home setting and would have a clinician supervising one or multiple users, who would be gradually exposed to their feared FoF situations until they habituate,

and their fears reduce. Unlike real-world exposure, it has lower physical risk and higher controllability of situations (Fromberger et al., 2018). Recent research suggests that VR via Head Mounted Displays (HMDs), which users wear as goggles, can successfully induce FoF in different populations, including those without existing FoF (Gui, 2021) and those with lower or higher levels of FoF. This demonstrates that VR is suitable for exposure work (Martens et al., 2017).

Though VR is also more immersive than serious games, some forms of VR, including HMDs, are more immersive than others. Formats such as interactive projector screens give a particularly immersive experience when treating FoF (Eloy et al., 2018). This is an emerging area, with technology developing rapidly, including recent wireless HMDs (e.g. Oculus Quest 2) to facilitate both ease of use and immersion.

1.2 Rationale for this review

Past systematic reviews related to this topic have mainly focused on serious games in general, less immersive forms of VR or the modification of non-psychological elements, such as balance and mobility (Corregidor-Sánchez et al., 2021; Dennett & Taylor, 2015; Kruisbrink et al., 2020; Neri et al., 2017). Neri et al.'s (2017) review reported that VR games were superior to conventional exercise interventions for FoF. They also reported poor methodological quality in most studies, noting particularly that nearly 90% of studies did not include follow-up periods (Neri et al., 2017). Other evidence suggests few significant benefits for use of non-VR serious games over physiotherapy at improving balance confidence (Dennett & Taylor, 2015). However, some of Neri et al.'s (2017) results included regular games, such as the Nintendo Wii balance board, which are categorised as "VR" (Singh et al., 2012). These are not fully immersive forms of VR, such as those using HMDs, but are often labelled as VR in the literature and therefore included in reviews on VR (Corregidor-Sánchez et al., 2021; Kruisbrink et al., 2020; Neri et al., 2017).

The present review focuses on less examined areas, including studies which use VR with fully immersive HMDs and are applied specifically to FoF in older adults, rather than physical balance. Older adults can be accepting of VR HMDs (Lin et al., 2018), however, the technology is generally more novel to them, with younger adults giving higher useability ratings for HMDs than older adults - possibly reflecting generational differences in attitudes towards technology (Plechata et al., 2019). Aims include examining evidence on user-engagement and acceptability in this older population, given that previous reviews have not focused on this.

1.3 Aims

- To examine the ways in which VR is used in relation to FoF.
- To review how outcomes relevant to FoF are measured.
- To summarise the findings and any treatment effects.
- To explore the acceptability of treatments and user-engagement levels.
- To report any barriers to implementation of VR for FoF.

2. Methods

This review followed the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement (Page et al., 2021). Data extraction and evidence synthesis was conducted in line with Popay et al.'s (2006) guidance on conducting narrative synthesis in systematic reviews.

2.1 Inclusion Criteria

Interventions using VR with HMDs were included, including male and/ or female participants with an average age of ≥ 60 years. Studies had to include psychological measures related to FoF, including those measuring FoF directly and indirectly. Such indirect measures of FoF can adequately assess state anxiety in response to a specific event, in this case, exposure to VR scenarios inducing FoF. Equally, they can measure confidence in abilities related to FoF, including balancing. Any experimental-design studies were included (i.e. when researchers introduce an intervention and study the outcome effects); these could include controlled trials and quasi-experimental studies.

2.3 Search Strategy

The online databases searched were MEDLINE, Embase, PsycINFO and Web of Science Core Collections. The searches spanned all dates the databases held papers for, with no limitation on publication date. (**Table 2**).

Table 1: Search terms used for databases

Target	Medline (Ovid)	Embase (Ovid)	PsycINFO (EBSCO)	Web of Science Core Collection
Population	<i>Searched manually</i>			
Problem	((fear* or phobia* or afraid or anxiet*) ADJ3 (fall* or balanc*)).tw.	((fear* or phobia* or afraid or anxiet*) ADJ3 (fall*or balanc*)).tw.	TI (((fear* or phobia* or afraid or anxiet*) N3 (fall*or balanc*))) OR AB (((fear* or phobia* or afraid or anxiet*) N3 (fall*or balanc*)))	TOPIC: ((fear* or phobia* or afraid or anxiet*) NEAR/3 (fall*or balanc*))
Intervention	<p><i>Mapped subjects:</i></p> <ul style="list-style-type: none"> • Virtual reality • Augmented reality • Video games (<i>Psychology subheading</i>) • Simulation training <p>Serious ADJ2 gam*.tw. (virtual or augment*) ADJ2 realit*.tw. <i>[Combined all above with OR]</i></p>	<p><i>Mapped subjects:</i></p> <ul style="list-style-type: none"> • Virtual reality [Explode] • Virtual reality exposure therapy • Augmented reality • Video games <p>Serious ADJ2 gam*.tw. (virtual or augment*) ADJ2 realit*.tw.</p>	<p><i>Mapped subjects:</i></p> <ul style="list-style-type: none"> • Virtual reality • Virtual reality exposure therapy • Augmented reality • Computer games <p>Serious N2 gam* TI (virtual or augment*) N2 realit* OR AB (virtual or augment*) N2 realit*</p>	<p>Serious NEAR/2 gam* (virtual or augment*) NEAR/2 realit* "Immersive virtual reality" [keyword]</p>

Further & Hand Searches

Guidance on conducting robust systematic reviews suggests performing forward and backwards searches to identify relevant work cited by suitable articles (Webster & Watson, 2002; Xiao & Watson, 2019), and reviewing past systematic reviews (Kitchenham & Charters, 2007). Over 600 studies were screened with four identified as suitable; these were already captured in the original search. From this original search, systematic reviews or meta-analyses studying interventions for FoF were also reviewed. One eligible study was identified which had been previously captured in the original search. Relevant reviews found via backwards and forwards searches of accepted papers were also examined. Five were identified as suitable, all of which were captured in the original search; therefore, no additional suitable studies were identified.

2.4 Quality Assessment

The final studies were assessed using the Joanna Briggs Institute (JBI) - Checklist for Quasi-Experimental Studies, which examines quality and risk of bias, for which studies are ultimately appraised as 'include' or 'exclude' across nine items. A second independent researcher (a Trainee Clinical Psychologist) also quality-assessed all studies to confirm inter-rater reliability in scoring. As recommended by the JBI manual, a pre-determined cut-off was decided between researchers, specifically that two-thirds of items be met for a study to be included in this review (Aromataris & Munn, 2020); meaning if over three out of nine criteria were not met or unclear, the study would be excluded. This was considered suitable to assess relevant studies in this niche emerging area of research. There was excellent agreement between researchers across all items ($k = 0.86$; weighted $k = 0.9$), resulting in confirmation that all studies were of good enough quality to include. (See **Table 3**).

3. Results

3.1 Outcome of Search Process

Seven studies were found to be eligible for this review by the primary researcher. The same second independent researcher replicated this search and screened the results, with duplicates removed, to ascertain inter-rater reliability of inclusion/ exclusion decisions. The second researcher agreed on the same final studies except for one, which they initially excluded, for the reason that they believed it did not measure FoF adequately (*Cohen's kappa* = 0.9). Researchers reached an agreement via discussion, choosing to ultimately include the study, as it adequately measured FoF indirectly.

3.2 Final studies

Figure 1: PRISMA Flow Diagram

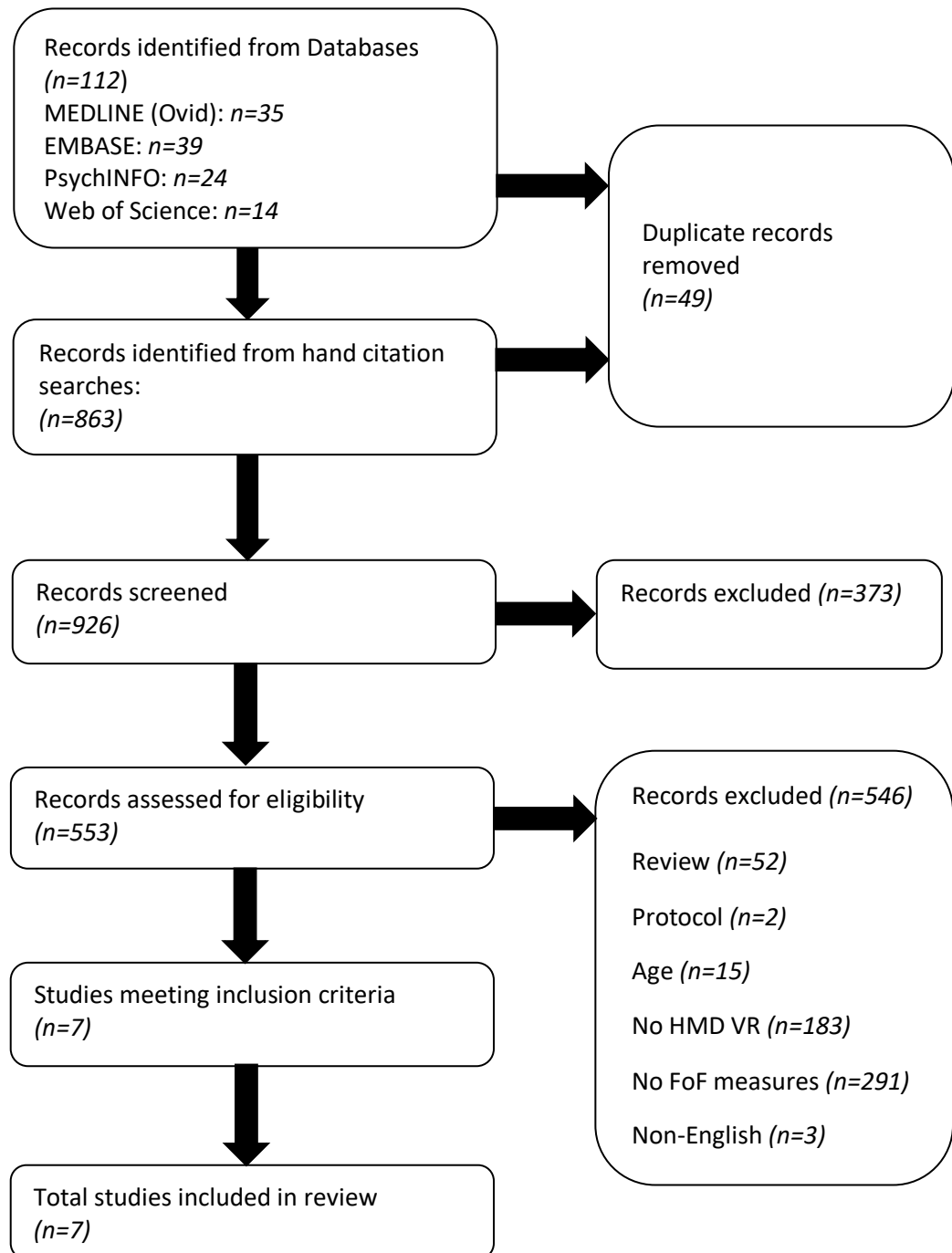


Table 2: Characteristics of included studies

Authors	N	Mean age (years) (SD) & Sex (% female)	Study design	Target condition	Treatment	Comparison	Length & frequency	FoF-related measurement & time-points	Main Analysis	Relevant results
Daga et al., 2017	61 (35 treatment; 26 control).	69 (± 11.2). 52%.	Cross-sectional. Baseline only measures.	Glaucoma patients.	VR: Presentation of static and dynamic visual stimuli, such as a moving tunnel, whilst participants were stationary.	VR. Healthy controls.	Three exposures of 2 minutes 15 seconds each, in one session.	University of Illinois at Chicago Fear of Falling Measure (16-item). Baseline only.	Tests of difference (<i>t</i> -test, Mann-Whitney). Linear regressions.	Significantly greater FoF in glaucoma group vs. controls ($P = .04$). Postural reactivity in response VR significantly associated with FoF in glaucoma group ($P = .009$; $R^2 = 18.8\%$). A multivariable model including age, gender, postural reactivity, number of falls in past year, and physical activity score, predicted specific increase in FoF units as postural

										<p>movements increased ($P = .001$; $R^2 = 48.8\%$) in glaucoma group.</p> <p>No effect sizes or degrees of freedom reported.</p>
Duque et al., 2013	<p>60 (30 treatment; 30 control).</p> <p>[Data error-also reports sample size as 70].</p>	<p>77 (± 9).</p> <p>62%.</p>	<p>Quasi-experimental. Pre and post measures.</p>	<p>Patients from Falls and Fractures Clinic.</p>	<p>VR: Visual-vestibular rehabilitation and postural training exercises/games.</p>	<p>VR. Patients from Falls and Fractures Clinic.</p>	<p>20-minute sessions, twice a week for six weeks; 12 total.</p>	<p>Survey of Activities and Fear of Falling in the Elderly (SAFFE). Baseline and nine months.</p>	<p>Tests of difference (t-test, ANOVA).</p>	<p>At 9 months: Significant reduction in falls in VR vs. controls group ($P = <.01$). Significantly lower FoF in VR vs. controls ($P = <.05$). Significantly improved balance parameters in VR group vs. baseline ($P = .01$).</p> <p>No effect sizes reported.</p>

<p>Ehgoetz Martens et al., 2017</p>	<p>42 (21 treatment; 21 control).</p>	<p>69 (±6). 38%.</p>	<p>Cross-sectional. Baseline only measures.</p>	<p>Parkinson's disease patients (high vs. low anxiety).</p>	<p>VR: High vs. low threat of falling, virtual environments , including walking on an elevated plank.</p>	<p>VR. Healthy controls.</p>	<p>10 exposures of 30 seconds each, in one session.</p>	<p>'Self-assessment Manikins' & State Anxiety Likert scale. Immediately post each exposure.</p>	<p>Tests of difference (<i>t</i>-test, ANOVAs).</p>	<p>Greater anxiety in high vs. low threat FoF situations by group ($F(2,39) = 8.32, p = .001$) and condition ($F(1,39) = 11.92, p = .001$). Significantly higher anxiety in both conditions for high anxiety group vs. other groups ($P = <.05$). Suggest that anxiety in Parkinson's increases cognitive processing, influencing balance control; particularly in highly anxious people.</p> <p>No effect size reported.</p>
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Giotakos et al., 2007	68 treatment.	77 (± 5). 54%.	Quasi-experimental. Pre and post measures.	Patients with hip fracture history and FoF.	VR: 'Virtual reality exposure scenario' (VRET), involving walkways, obstacles, movement training and shopping task with a treadmill.	No control group. Baseline vs. post-intervention.	Three ten-minute weekly sessions and booster session at 6 months.	Falls Efficacy Scale-International (FES-I). Activities-specific Balance Confidence scale (ABC). Baseline, immediately post intervention, six months and a year.	Tests of difference (MANOVA).	97% had significantly lower FoF at 12 months vs. high FoF at baseline ($P = <.001$). Lower balance scores were predicted by FoF ($P = <.05$). FoF, or related anxiety following hip fracture, may be 'significantly mitigated' by VRET scenario. No effect size reported.
Griffin et al., 2011	26 treatment.	64 (± 6.7). 15%.	Quasi-experimental. Pre and post measures.	Parkinson's disease patients.	VR: Walking task simulating real world challenges, incorporating FoF triggers, including obstacles vs. open ground.	No control group. Baseline vs. post-intervention.	Six exposures total without time limit, in one day.	FoF Visual Analogue Scale (VAS). Immediately after each exposure.	Tests of difference (ANOVA).	Significantly greater FoF in VR conditions with obstacles vs. open ground ($F(1,18) = 11.7, p = .003$). Low overall FoF in all conditions. No significant interaction of condition and terrain

										<p>($F(2.24,40.3) = 1.26, p > .2$).</p> <p>No effect size reported.</p>
<p>Levy et al., 2016</p>	<p>16 (9 treatment; 7 control).</p>	<p>71 (± 15.7). 63%.</p>	<p>Quasi-experimental. Pre and post measures.</p>	<p>Participants with FoF.</p>	<p>VR: navigating virtual environments of increasing difficulty (e.g. steps, obstacles), whilst sat in swivel chair.</p>	<p>Waiting list controls, with FoF.</p>	<p>12 weekly sessions of 40 minutes each.</p>	<p>University of Illinois at Chicago Fear of Falling Measure (19-item). Within a week both pre- and post-intervention.</p>	<p>Tests of difference (Mann-Whitney, Fisher's exact).</p>	<p>Significantly greater decrease in VR's FoF vs. controls post-intervention ($P = .007$). Treatment group ($M = 6.44, SD = 3.17$) and controls ($M = 6, SD = 1.15$) were impaired socially due FoF according to Sheehan Disability Scale. Suggest that VR therapy, associated with serious gaming, appears feasible for treating FoF.</p> <p>No effect size reported.</p>

Phu et al., 2019	195 (63 treatment one; 82 treatment two; 50 control).	Median= 78 (interquartile range= 72-83). 67%.	Quasi-experimental. Pre and post measures.	Patients with balance deficits or falls history.	Treatment one- VR: Postural training and rehabilitation games, such as reaching for objects. Treatment two: Group-based Otago Exercise Programme (OEP) for falls prevention.	Controls were participants who declined interventions.	20-minute sessions, twice a week for six weeks; 12 total.	FES-I. Baseline and immediately post-intervention.	Tests of difference (Fisher's exact).	Significant reduction in FoF post-intervention vs. baseline in VR (P = .004) and exercise (P = .013) groups; largest FoF reduction of 16% in exercise group vs. 11% in VR, though no significant difference between these. No significant change in control group. No effect sizes reported.
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Table 3: Quality assessment tool

The Joanna Briggs Checklist for Quasi-Experimental Studies (non-randomised experimental studies)

Study	1. Is it clear in the study what is the 'cause' and what is the 'effect' (i.e. there is no confusion about which variable comes first)?	2. Were the participants included in any comparisons similar?	3. Were the participants included in any comparisons receiving similar treatment/care, other than the exposure or intervention of interest?	4. Was there a control group?	5. Were there multiple measurements of the outcome both pre and post the intervention/exposure?	6. Was follow-up complete and if not, were differences between groups in terms of their follow-up adequately described and analysed?	7. Were the outcomes of participants included in any comparisons measured in the same way?	8. Were outcomes measured in a reliable way?	9. Was appropriate statistical analysis used?	Overall appraisal
Daga et al., 2017	N/a (use of regression, not cause and effect)	Yes	Yes	Yes	N/a (exploring relationships not effects)	N/a (no follow-up measures after intervention)	Yes	Yes	Yes (appropriate test used- but no effect sizes or degrees of freedom reported)	Include

Duque et al., 2013	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes (but same physiotherapist conducted all measures)	Yes (appropriate test used- but no effect sizes reported)	Include
Ehgoetz Martens et al., 2017	Yes	No (high FoF group had significantly greater depression than other groups)	Yes	Yes	Yes	Yes	Yes	Unclear (no mention who conducted STAI)	Yes (appropriate test used- but no effect sizes reported)	Include
Giotakos et al., 2007	Yes	N/a (repeated measures)	N/a (same group)	No	Yes	Unclear (all participants completed FES-I- no mention if everyone completed ABC at follow-up)	Yes	Unclear (questionnaires 'self-administered'- does not say who conducted this or if they were trained)	Yes (appropriate test used- but no effect sizes reported)	Include
Griffin et al., 2011	Yes	N/a	N/a	No	Yes	Yes	Yes	Unclear	Yes	Include

		(repeated measures)	(same group)					(no inter-rater measures for video gait observations)	(appropriate test used-but no effect sizes reported)	
Levy et al., 2016	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Unclear (no mention of who conducted measures)	Yes (appropriate test used-but no effect sizes reported)	Include
Phu et al., 2019	Yes	Yes	Unclear (recruited from various hospitals/GPs)	Yes	Yes	Yes	Yes	Yes	Yes (appropriate test used-but no effect sizes reported)	Include

Possible outcomes: Yes, No, Unclear, N/A. Studies had to meet at least two-thirds of criteria to be included. Criteria which were not met or were unclear are highlighted in red. Criteria which were met overall, but with caveats or additional points, are highlighted in yellow.

4. Review of Study Findings

The studies included a range of sample sizes ($M = 68$, $SD = 55$, Range = 16-195), with one study reporting conflicting information on this as a data-entry error (Duque et al., 2013). Participants were 72 years old on average ($SD = 4.9$), with an average of 50% females across all samples. Other sample demographics varied considerably, with two studies including participants with Parkinson's disease (Ehgoetz Martens et al., 2017; Griffin et al., 2011), one using glaucoma patients (Daga et al., 2017) and the remaining four recruiting those with a history of falls, balance deficits and/ or FoF. Two of the latter studies also specified a history of fractures from falling (Duque et al., 2013; Giotakos et al., 2007). All studies used tests of difference when analysing FoF, including t -tests and ANOVAs, with one conducting linear regression (Daga et al., 2017). Only one study (Daga et al., 2017) reported data on ethnicity, with 54% Caucasian, 34% African American, and 12% Asian or 'Other'. Five of the studies (71%) also had control groups, with the remaining using pre- and post-intervention measures of one group (Giotakos et al., 2007; Griffin et al., 2011). Although this review focuses on FoF as a psychological outcome, other non-psychological measures were used in the studies, including balance, posture, grip strength and 'freezing of gait', which is a temporary perceived inability to step forward (Nutt et al., 2011).

The following review of the studies is categorised into the main review aims, as outlined above.

4.1 How VR is used in relation to FoF

Not all studies used VR to primarily treat FoF, with it often being a related factor or secondary outcome. This reflects the use of VR in FoF via HMDs being an emerging area. Methods of VR's application were also variable, with total

number of sessions across studies varying from one to 12 ($M = 9$, $SD = 4.1$). The length of these individual sessions also spanned from 30 seconds (s) to 40 minutes (m) ($M = 15.5m$, $SD = 15m$), with total exposure time of all sessions varying from 5m to 8 hours (h) ($M = 2.8h$, $SD = 2.9h$). Just two studies clearly used VR to directly treat FoF, the first of which used treadmills and virtual walking environments, with obstacles requiring postural adjustments (Giotakos et al., 2007; Levy et al., 2016). They particularly highlighted cognitive aims to increase self-efficacy beliefs around falling, which not all studies did. The second study was the only one to use seated VR and incorporate serious games on the PlayStation Eyetoy, with graded exposure tasks including navigating narrow corridors (Levy et al., 2016). A further two studies used VR interventions for primarily balance rehabilitation. Duque et al. (2013) and Phu et al. (2019) used visual and postural training tasks of increasing difficulty, involving leaning. The tasks were also tailored to the person in Phu et al.'s (2019) study. Taking a graded exposure approach, task difficulty or time of exposure increased with progression. Graded exposure was present in most studies in some form, though one study only used two grading categories: 'high' and 'low' FoF situations (Ehgoetz Martens et al., 2017).

Four of the studies included those with falling histories or FoF (Duque et al., 2013; Levy et al., 2016; Phu et al., 2019), with the remaining three focusing on Parkinson's Disease and glaucoma, for whom FoF can be exacerbated. This suggests VR could be applied across health conditions common in older people. One study used VR primarily to measure the effects of visual cues on gait in Parkinson's, with FoF measured post-exposure (Griffin et al., 2011). Ehgoetz Martens et al. (2017) examined effects of anxiety, induced by VR situations, on balance control in Parkinson's, as a loss of balance predicts falls (Adkin et al., 2002). Daga et al. (2017) similarly investigated relationships between FoF in Glaucoma participants and postural reactivity. Overall, despite all utilising VR via HMDs, the interventions differed in multiple ways, including content and exposure-length; there was no 'typical' VR FoF intervention. Some involved participants remaining stationary or sitting (Daga et al., 2017; Levy et

al., 2016), whilst others required they move on treadmills (Giotakos et al., 2007). The stimuli they experienced through HMDs was likewise diverse, although most utilised games simulating real world challenges that their demographic might face. For instance, one study engaged participants in walking tasks along narrow walkways in high and low threat situations, specifically being lower to or higher from the ground (Ehgoetz Martens et al., 2017), whilst another required participants to step over boundaries on the floor (Griffin et al., 2011).

4.2 How outcomes relevant to FoF are measured

All studies used measures relating to FoF and direct or indirect measures were included due to the emerging nature of this area. Six of the studies used one measure and one study used two. All were self-report questionnaires, unlike more objective physical balance measures such as force platforms (Daga et al., 2017). The measures used were as diverse as the VR application, with seven measures utilised in total, the Falls Efficacy Scale-International (FES-I) (Yardley et al., 2005) being used twice and all others once.

The FES-I, comprised 16 items examining everyday activities which might induce FoF, including cleaning or shopping, scored on a 10-point scale of falling 'concern'. It is a widely used, high-quality measure and is sensitive to change in clinical interventions (Moore & Ellis, 2007). Phu et al. (2019) and Giotakos et al. (2007) used this, with the latter also using the Activities-specific Balance Confidence scale (ABC) (Powell & Myers, 1995). This is a 16-item questionnaire rating confidence in ability to keep balanced in certain situations as a percentage, with '100%' being totally confident; again, items cover everyday tasks like cleaning. Levy et al. (2016) used a version of the University of Illinois at Chicago Fear of Falling Measure (FFM), which assessed FoF on a four-point scale of 'worry' across 19 activities, including getting out of bed. Daga et al. (2017) was the only study meeting inclusion criteria which measured FoF

at baseline only. They used an updated 16-item version of the FFM, comparing scores with postural metrics gained via VR and force platforms. This questionnaire is measured on a three-point scale of 'worry' and covers similar situations, including walking outside. This latter version of the FFM was created after a detailed analysis determined that users could not discriminate certain categories on the scale, therefore reducing the Likert from four to three-points (Moore & Ellis, 2007; Velozo & Peterson, 2001); it is not explained why Levy et al. (2016) did not use this updated version of the measure. Duque et al. (2013) utilised the Survey of Activities and Fear of Falling in the Elderly (SAFFE), which has 11 items on four-point Likert scales of FoF, covering activity restriction and QoL.

Most of these measures had been validated and had reportedly high test-retest reliability, including the ABC (intraclass correlation coefficient [ICC] = 0.93), the FES-I (ICC = 0.96) and the SAFFE (ICC = 0.91) (Liu & Ng, 2019; Shah et al., 2017; Yardley et al., 2005). More limited support was found for the 19-item FFM, with their scale being poorly supported empirically before being updated (Velozo & Peterson, 2001). There were also no reliability statistics for both versions of this measure, though Moore and Ellis (2007) posit that a strength of the FFM is that the items were developed by older people, unlike the other measures. Overall, there was significant variation, though all questionnaires covered feasible situations older people might face. The remaining two studies used simpler measures. Ehgoetz Martens et al. (2017) indirectly measured FoF via a 9-point Likert scale of State anxiety imposed onto 'Self-assessment Manikins' (SAMs), which are pictures of faces displaying various distress levels; this was measured immediately post-exposure to FoF situations. SAMs are a validated approach in the measurement of state anxiety, although they have poor to reasonable reliability for this (ICC = 0.55-0.78) (Nazari et al., 2012). Griffin et al. (2011) used a 10-point Visual Analogue Scale (VAS) directly measuring FoF after each VR exposure session. No explanation was given for why they chose VAS when more detailed measures exist, though it was likely faster to implement due to fewer items. Validity and reliability are reportedly

poor to reasonable for the VAS in measuring FoF (ICC = 0.49-0.64) (Scheffer et al., 2010). Overall, follow-up periods were also short, ranging from no follow-up, to 12 months. One study had a follow-up at six and 12 months (Giotakos et al., 2007) and another at nine months (Duque et al., 2013). One was measured at baseline only (Daga et al., 2017), with the remaining conducted immediately following VR exposure (Ehgoetz Martens et al., 2017; Griffin et al., 2011; Phu et al., 2019), other than Levy et al. (2016), who followed-up within a week post-exposure. The JBI quality assessment also found that not all follow-ups were clearly reported, with Giotakos et al. (2007) not clarifying if all participants completed the ABC.

4.3 Findings and Treatment effects

The findings varied greatly due to differences in study design, population and specific FoF measures, with some being primary or secondary outcomes. Due to their diversity, the studies are first described individually below and then synthesised.

Using VR alongside serious games to directly treat FoF, Levy et al. (2016) reported significantly lower FoF scores in the VR intervention group versus controls, though no effect size is reported. They concluded that VR associated with serious games can be successfully utilised in FoF treatment, noting that the approaches are complementary. However, they randomised participants via drawing lots, making this study quasi-randomised. Giotakos et al. (2007) likewise measured FoF as a primary outcome, alongside balance confidence. They reported a high 'success rate', with 66 out of 68 participants experiencing significant FoF reductions, from 'high' to 'low' FoF, at 12 months. Balance confidence also increased over time from baseline (M = 48%), to six (M = 68%) and 12 months (M = 88%). Again, no effect-sizes or significance statistics are reported for this, making it challenging to interpret. Based on their results, they

suggest VR is an effective platform for the development of FoF treatments, though the basis for this is questionable.

Phu et al. (2019) concurred with this view and had the largest sample of 195, with three groups: VR, exercise and control. The JBI flagged that, unlike the other studies, it was unclear whether these groups received similar care outside the intervention variable, partly as they were recruited from various hospitals and GPs. This might have introduced unknown biases into the results. The primary outcome was physical balance, though there was a significant reduction in FoF in both VR and exercise groups immediately post-intervention, versus baseline. Controls showed no significant FoF change over these six-weeks. FoF was significantly lower in the VR group versus controls, though no significant difference between interventions groups was reported and no effect sizes were reported either. As with some of the studies, there was also no longer-term follow-up, meaning it is unknown if any benefits were sustained. Additionally, this study did not randomise participants, indicating potential bias. Overall, they advocated for the use of VR as being an effective alternative in FoF treatment, at least in the short term.

Primarily exploring balance outcomes, Duque et al. (2013) found significant reductions in FoF and falls frequency in the VR group versus controls at 9-months, again, no effect sizes were reported for this. As noted in the JBI, they reported one physiotherapist as conducting multiple measures of posture, which could have benefitted from a secondary rater; this physiotherapist also conducted the FoF questionnaire. However, the clinicians who conducted the VR training were different from those conducting the assessments, reducing risk of bias somewhat. Reporting also could have been clearer in other areas, with the randomisation method for group allocation not being identified.

Daga et al. (2017) investigated relationships between FoF and posture in glaucoma patients via VR, versus healthy controls. They reported significantly greater FoF in glaucoma patients at baseline. Postural reactivity in response to VR, such as leaning, was significantly associated with FoF in glaucoma participants, but not in controls. Their linear regression univariate model predicted specific increase in FoF units as postural movements forward and backwards increased ($P = .009$; $R^2 = 18.8\%$); a limitation however, is that they did not report the degrees of freedom or effect size. Another improvement they acknowledged would be to include multiple FoF measures in their regressions, rather than just one, to strengthen their findings.

Griffin et al. (2011) evaluated the effects of VR visual cues on the gait of those with Parkinson's, with intention to improve their walking. FoF was a secondary measure to freezing of gait. There were low levels of FoF across VR conditions, including those with obstacles, though there was significantly greater FoF in the presence of obstacles versus without. Although their ANOVA was otherwise reported in full, no effect size was reported for this. Specific VR conditions, including floor lines to cue walking, also did not significantly influence FoF. They conclude that some VR cues, specifically transverse lines, can be effectively used to improve walking, whilst keeping FoF levels manageable. A limitation of their use of VAS to measure FoF is the need for clear vision and precise writing ability when answering, unlike other measures which could be read by someone else if necessary. Ability to use a pen could be especially impaired in those with Parkinson's. As previously noted, their decision to use VAS over other more detailed FoF measures is not explained.

The final study likewise used participants with Parkinson's (Ehgoetz Martens et al., 2017), using Likert scales indirectly measuring FoF via state anxiety, immediately following VR exposure. There were two conditions, high and low FoF threat, with three groups: those with high FoF, low FoF and controls. Participants were assigned to these groups based on their baseline anxiety

score, with those scoring above a threshold assigned to the high FoF group. All participants reported significantly greater anxiety when exposed to the high threat VR condition, versus the low threat condition. The high FoF group reported significantly higher anxiety across both low and high threat conditions, versus both controls and those in the low FoF group. Again, no effect sizes were reported for the findings of the ANOVAs. In the high threat condition, only the high FoF group reported increasing anxiety as trials progressed, whilst the low FoF group, and controls, had steady anxiety levels throughout the exposure. Despite being immediately post-exposure, the Likert anxiety measure was not specific to FoF, measuring it only indirectly. Also, due to an inability to match groups on all mental health traits, the high FoF group had significantly greater depression than other groups, as highlighted in the JBI, which could confound results.

Overall, the studies generally concluded that VR might be useful in treating FoF, including in samples with health conditions, and this seemed related to improvements in balance. VR obstacles also appeared to induce FoF and those with higher existing anxiety found that VR induced more FoF, versus those with lower baseline FoF. The studies did use and report appropriate analyses, as identified through the JBI. All used tests of difference, including *t*-tests, Fisher's exact, Mann-Whitney, ANOVAs and MANOVAs; only one study examined relationships, specifically between postural reactivity and FoF using Linear regression (Daga et al., 2017). However, there were significant quality issues which challenge the validity of these results. Reporting of their FoF analyses was overall fairly brief, partly as other non-FoF outcomes were focused on such as gait and grip-strength (Phu et al., 2019). Despite reporting significant results, none of the studies reported the effect size of their findings. It is crucial that *p* values are accompanied by effect sizes to provide full context (Sullivan & Feinn, 2012), which was not the case.

The JBI also emphasised issues concerning how reliably the FoF questionnaires were conducted. For instance, Ehgoetz Martens et al. (2017), Giotakos et al. (2007) and Levy et al. (2016) do not clarify who conducted the measures nor whether they were trained in this. Additionally, shorter follow-up periods also mean the evidence is limited regarding longevity of any effects, though these effects cannot clearly be established in the first place, given the lack of effect sizes. Another issue is that these results are challenging to compare and synthesise, due to the lack of consistency in FoF measurement. Though five studies used controls, true randomisation was also not reported in the studies, introducing bias into the findings. Nonetheless, group randomisation was not a prerequisite for inclusion in this review.

4.4 Treatment Acceptability and User-engagement Levels

The studies generally did not explicitly report participants' qualitative acceptance of VR interventions, though other factors including drop-out rates and their reasons, can be explored. Overall, VR seemed to be well accepted, with high adherence. Phu et al. (2019) reported adherence rates of 72% in the VR group, akin to the non-VR exercise group at 71%. Griffin et al. (2011) also reported a high adherence rate of 85%, with one participant withdrawing due to "discomfort", which was not elaborated on. Duque et al. (2013) reported 97% adherence, with drop-out due to "logistics problems" in attending sessions, not due to aversion to VR itself; again, this reason was not explained. Remaining studies did not explicitly refer to drop-out rates, but all participants completed the VR interventions and were included in their analyses, suggesting good treatment adherence (Daga et al., 2017; Ehgoetz Martens et al., 2017; Giotakos et al., 2007; Levy et al., 2016).

Phu et al. (2019) mentioned that their VR stimulus could be individually customised according to participants' ability to tolerate it, such as changing the intensity of postural training games as people habituated. Moreover, Phu et al.

(2019) reported that this customisable content and one-on-one nature of the intervention enhanced peoples' engagement. Duque et al. (2013) also progressively increased the complexity of VR training games as participants reported higher confidence; they concluded that their intervention was "well-accepted" by participants. Griffin et al. (2011) also emphasised the necessity for HMDs to be unobtrusive, comfortable and to not contribute to FoF or reduced balance confidence.

4.5 Barriers to Implementation

As described, user-engagement levels were reportedly good across studies. Drop out reasons were not always reported nor explained, but included discomfort, inability to physically complete tasks and logistical issues attending (Duque et al., 2013; Griffin et al., 2011). These barriers were both related and unrelated to the VR interventions, though few others were explicitly discussed. Promisingly, VR-induced side-effects for instance were not reported in any study. Phu et al. (2019) explained that barriers personal to participants such as tiredness and low motivation could contribute to low adherence, particularly in VR interventions which combine physical activity. Duque et al. (2013) concurred, reporting that real-world implementation of such exercise-related interventions could be challenging, as they require physical endurance which some older adults might not have. Levy et al. (2016) demonstrated that VR treatments for FoF could be conducted with participants sitting down however, reducing physical fatigue.

5. Discussion

There was large variation between studies on numerous factors, including the sample population, FoF-related measures, study design, sample size and specific VR intervention. This inevitably makes comparing and synthesising findings more challenging. However, some issues are relevant across all VR

studies, for instance, it is difficult to blind participants to a VR versus non-VR treatment in such studies. 'Treatment as usual' for FoF also varied, for example in one study it involved: an invitation to join an exercise group, medication reviews, healthcare professional home visits, hearing and visual assessments, nutritional or vitamin supplements and psychoeducation on falls prevention (Duque et al., 2013). Not all studies had controls with this variety of support, again, making comparison challenging and reflecting the different health service contexts the research took place in.

5.1 How VR is used in relation to FoF

There was no typical VR intervention for FoF, moreover, only a minority of studies actually used VR to directly treat FoF (Giotakos et al., 2007; Levy et al., 2016). Most measured FoF as a secondary outcome and focused on objective balance rehabilitation, which could be due researchers' desire to rely less on time-consuming self-report questionnaires (Perez-Jara et al., 2010). Some concentrated on the mitigation of symptoms relating to specific conditions, including freezing of gait in Parkinson's disease (Griffin et al., 2011). This highlights the prevalence of FoF in disorders like Parkinson's and Glaucoma, as well as in older people generally. Some involved participants remaining stationary or sitting (Daga et al., 2017; Levy et al., 2016), whilst other interventions conversely used treadmills (Giotakos et al., 2007). VR was also not purely used, with Levy et al. (2016) including non-VR serious games, further convoluting cross-study comparisons of HMD usage in VR. The actual stimuli via HMDs likewise differed, although most opted for content simulating real-world challenges that their demographic might face, presented in a graded manner, including reaching, leaning or navigating objects. The HMD technology also varied, including V8 head-mounted displays (Levy et al., 2016) or KEO - Proview XL-50 (Giotakos et al., 2007). These varied by weight, head straps, screen type and size, emphasising the variety of VR available. Although only three studies reported adherence (Duque et al., 2013; Griffin et al., 2011; Phu et al., 2019), it was good when reported, suggesting these various HMDs were mainly tolerable to older people, as in past research (Lin et al., 2018). The

varied exposure length and session numbers reflects VR's potential versatility in application, though no session was wider than a week apart. Despite this, the generally incomplete reporting of findings outside of *p* values means the optimal exposure format for most effectively treating FoF remains unclear.

5.2 How outcomes relevant to FoF are measured

The methods of FoF measurement varied greatly, all being self-report. Most studies used just one measure, with seven different measures being used across all studies. The FES-I was the only questionnaire used twice. Only one study measured FoF indirectly, which is less precise than direct measurement. In any case, FoF is challenging to measure according to past review evidence, with much research using just one question to assess it; this needs to be improved to ensure adequate FoF assessment (Perez-Jara et al., 2010). The JBI also highlighted that reporting on who conducted these measures, and if they were adequately trained, should be clarified in these studies to reduce bias and enhance transparency (Ehgoetz Martens et al., 2017; Giotakos et al., 2007; Levy et al., 2016). Scales commonly used in other research include the ABC and FES-I (Moore & Ellis, 2007), both of which were present once and twice respectively (Phu et al., 2019; Giotakos et al., 2007). These longer, detailed scales are more suitable for measuring responses to FoF interventions but are often not utilised due to the time required (Perez-Jara et al., 2010). Most studies in the present review used measures in addition to FoF, such as balance, meaning shorter scales might have fitted better into their design, particularly if participants were also engaging in intensive VR. Nonetheless, improvements could still be made; Levy et al. (2016) for example did not use the updated 16-item version of the FFM, which has been found to have better validity than the previous version (Veloza & Peterson, 2001), as used by Daga et al. (2017). Ehgoetz Martens et al. (2017) also opted to use SAMs with imposed Likert scales, which have relatively low reliability and validity versus other specific FoF measures (Nazari et al., 2012). In all cases, the choice of FoF measure was not fully explained, reducing both replicability and transparency in the research process.

A possible reason for the differing FoF measures used is the lack of consensus on a definition (Jung, 2008). It has been suggested that the subjective nature of FoF measurement can be helped by also measuring activity restriction, an objective FoF consequence (Perez-Jara et al., 2010). Since FoF was often measured secondary to other objective balance measures, this raises the question around whether researchers should focus on self-report outcomes like FoF, or more objective measures. A combination of both might reflect users' experience best (Perez-Jara et al., 2010), which was conducted in multiple studies, including via force platforms, and were found to be correlated (Daga et al., 2017). This relative strength of combined measurements could have been better highlighted if they had improved their reporting of statistics, including effect sizes. Despite these studies representing an emerging niche in FoF treatment, coherency and comparability in research is still essential, including of outcome measures and reporting of results.

Moreover, follow-up periods for FoF were mostly conducted immediately following VR exposure; longer follow-ups would improve the research quality and give better indication of maintained benefits. As found in the JBI, follow-ups could have been better reported, with Giotakos et al. (2007) not clearly reporting whether all participants completed the ABC at follow-up for instance. Before further research examines longer follow-up periods, the reporting of results must be improved to establish the size of the effects of VR on FoF in the first place. It is crucial that studies report effect sizes, and degrees of freedom where necessary, to enhance the quality of the evidence-base in this area (Sullivan & Feinn, 2012).

5.3 Findings and Treatment effects

The studies resulted in unique findings given their diverse aims, design, sample population and FoF measures. For instance, the diverse samples highlight FoF differences across health conditions, including higher FoF in glaucoma patients versus controls (Daga et al., 2017). Despite this, there were many significant quality issues in the findings. Most utilised experimental designs with control groups and reported findings initially appeared positive. Multiple studies described significant reductions in FoF following VR intervention, versus controls (Duque et al., 2013; Levy et al., 2016; Phu et al., 2019) or their own baseline (Giotakos et al., 2007). Other notable results included greater FoF in the presence of virtual obstacles compared to without (Griffin et al., 2011) and prediction via regression of increases in FoF, as postural imbalance increased (Daga et al., 2017). One study also found that low threat VR FoF situations induce high anxiety in more anxious older people (Ehgoetz Martens et al., 2017). As outlined previously, the validity of all these findings is questionable given the standard of reporting in the results sections, with none reporting effect sizes. Therefore, the magnitude of these significant effects is unknown. Although some samples were large, most were also relatively modest, further challenging the generalisability their findings. As discussed, follow-up lengths were generally short-term, meaning longer-term benefits of FoF interventions are yet to be explored further. Multiple studies explicitly concluded that VR via HMDs is an effective and promising platform for FoF intervention (Levy et al., 2016; Giotakos et al., 2007; Phu et al., 2019), even if used alongside serious games (Levy et al., 2016). Although review evidence supports this, finding that VR interventions are superior at improving FoF than traditional treatments, including balance exercises (Neri et al., 2017); these conclusions are not yet adequately supported by the quality of the reported results in the present studies.

5.4 Treatment acceptability and user-engagement levels

Adherence rates were good for studies which reported them, ranging from 72-97% in VR groups (Duque et al., 2013; Griffin et al., 2011; Phu et al., 2019). However, not all studies reported this, which is necessary to ensure quality and

transparent research. Although other drop-out rates were not explicitly mentioned, all participants completed interventions for the other studies (Daga et al., 2017; Ehgoetz Martens et al., 2017; Giotakos et al., 2007; Levy et al., 2016). A general benefit of VR is that virtual environments are adaptable to individuals' needs and this customisation could logically result in better adherence and acceptance of interventions. Some studies allowed customisable content according to participants' progress, which reportedly increased engagement and acceptance levels (Duque et al., 2013; Phu et al., 2019). These good retention rates are reflected in other research; one study found that retention of technology-based FoF interventions, including serious games, exceeded regular exercises at three-months (Kwok & Pua, 2016). A review also reported high engagement levels in technology-based balance and exercise interventions in older adults (Valenzuela et al., 2018).

One study emphasised the importance of HMDs being unobtrusive and themselves not increasing FoF (Griffin et al., 2011). Research suggests that intention to use VR HMDs is positively predicted by perceived usefulness, enjoyment and usability (Mascret et al., 2020). More recent introductions of lighter wireless HMDs logically aid this perceived usability and unobtrusiveness, such as the Oculus Quest 2.

5.5 Barriers to implementation

Participant discomfort, inability to physically engage and logistical issues in attending were the only adherence barriers reported (Duque et al., 2013; Griffin et al., 2011); these could have been more fully explained to ensure future studies can address them. Home-based VR treatment might remedy any issues attending for instance. As outlined, HMD-related discomfort can also be minimised through use of wireless HMDs. HMDs are also relatively affordable, making cost an increasingly minimal barrier, especially considering they can be used many times. They also require fewer clinicians to supervise multiple users

engaging in semi-automated VR interventions, thus potentially saving labour costs (Freeman et al., 2018).

Physical exhaustion can be another barrier for older adults in physically active interventions (Forkan et al., 2006; Rhodes et al., 1999). Promisingly, this was not reported in the study samples, albeit some involved sitting (Levy et al., 2016). Although sitting VR interventions might reduce the barrier of physical fatigue, they could simultaneously reduce opportunities to strengthen balance-related muscles. Differences in the use of additional force platforms or hand-held controllers could also hinder the implementation of VR in older adults. For instance, those with arthritis might have issues holding controllers, though this was not reported as a barrier in the studies.

Furthermore, as Duque et al. (2013) notes, blinding in VR studies is often unfeasible, which could be interpreted as a barrier to producing the strongest evidence base for VR for FoF. Similarly, although many FoF measures have been developed, most studies only used one, with few studies using the same measures. Some even opted for outdated measures or those with poorer reliability (Ehgoetz Martens et al., 2017; Levy et al., 2016), a significant barrier to evaluating the effectiveness of VR when reviewing the evidence. Daga et al. (2017) also highlighted this need to further validate findings using multiple FoF measures before further implementation of VR in real-world settings.

5.6 Limitations

This review has some limitations; firstly, the sample populations included were heterogenous in factors other than 'older' age, making it challenging to synthesise and make generalisations on this topic. For example, comorbidities included Parkinson's disease and glaucoma. A meta-analysis was also not possible given the varying study designs and outcomes. Although the quality

assessment matched the study designs well and the approach recommended by the authors was followed (Aromataris & Munn, 2020), it had no objective cut-off score, being determined instead by the reviewers.

5.7 Areas for Future Research and Clinical Practice

There is a pressing need for further consensus on a definition for FoF (Jung, 2008), which would potentially remedy the use of many different measures across studies, making comparisons difficult. The use of multiple reliable FoF measures in studies would also strengthen findings, though issues including time limitations might contribute to such decisions (Perez-Jara et al., 2010). Activity restriction could be measured as a more objective adjunct to FoF to address the subjective nature of FoF measurement (Perez-Jara et al., 2010). Overall, a key area of improvement is the reporting of results, as emphasised in the JBI, as none of the studies outlined the effect sizes of any significant differences, leaving the evidence-base currently weak regarding VR for FoF. Specifically who conducted the measures, and their training, should also always be reported. Follow-up periods were mostly immediately following VR exposure and longer follow-ups would provide better indication of maintained benefits. The studies were also quasi-randomised and greater true randomisation would reduce potential bias.

6. Conclusion

The diverse content and focus of the VR interventions in these studies inevitably reflects the emerging nature of this area. When directly addressing FoF, most studies used tasks simulating real world challenges older people might face in-vivo. Many FoF measures with varying reliability were used and this reflected the lack of consensus on a FoF definition; this somewhat convolutes and weakens the evidence-base. Though the results would suggest

that VR treatment via HMDs is beneficial for FoF in the short-term, the quality of reporting was not adequate to merit this conclusion yet. Better reporting of effect-sizes, larger sample sizes, detailed multiple FoF measures and longer follow-ups are necessary. VR for FoF was generally well accepted by older adults across various conditions, including sensory disorders and age-related balance decline, though adherence-levels should be more consistently reported. Few implementation barriers were also reported, other than participant discomfort by a minority. Past research suggests that VR therapy is already as effective at improving anxiety as in-vivo therapy (Carl et al., 2019). Given the additional need for reduced labour costs in such psychological interventions (Freeman et al., 2018), these semi-automated VR treatments may also have potential in the treatment of FoF and therefore it is worth continuing to strengthen this evidence-base to better determine this.

7. References

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CHAPTER 2: Major Research Project

Augmenting psychological treatment for fear of falling using Virtual Reality: A feasibility study in older adults

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Plain English Summary

Title

Augmenting psychological treatment for fear of falling using Virtual Reality: A feasibility study in older adults

Background

Falls in older adults are expensive to the NHS and reduce quality of life. A third of older adults (≥ 65 years) fall annually, increasing with age. Fear of falling (FoF) is a reduced confidence in balancing abilities, usually associated with reduced daily activities and exercise. This can develop whether people have had past falls or not and can increase falling risk through impaired balance abilities. This heightened anxiety negatively affects attention relating to movement. Given the role of these psychological processes, Virtual reality (VR) exposure treatments can potentially improve FoF and reduce clinician labour. Moreover, few VR treatments have been designed co-productively.

Aims

To evaluate older people's perceived acceptability, tolerability and feasibility of a VR FoF exposure intervention. To determine if these patients are willing to participate in actual VR.

Methods

Older people with current or previous FoF from NHS Glasgow Psychology services received visual and written information on a VR intervention, involving

exposure to feared scenarios. This was designed alongside Clinical Psychology experts, service-users and Computer science colleagues. Participants engaged in semi-structured telephone interviews, providing feedback, including perceived tolerability, feasibility and acceptability. These were analysed via qualitative thematic analysis. They also completed mental health measures on anxiety, mood and FoF.

Main findings & Conclusions

Ten sub-themes were found within four overarching themes. Additional comments emphasised fall experiences, physical health, motivation and effects of COVID-19 on exercise. Results suggested older people are mainly positive and willing to engage in VR for FoF. Most could envisage it in usual treatment. Implications for intervention development included increased reassurance from clinicians, clear explanation of technology, more VR tasks outside the home and adaptations for health conditions. Recruiting participants via clinicians was effective. Future research should improve VR content and test in-vivo with larger samples; effort should be made to include more diversity, including males, non-white ethnicities and lower socioeconomic backgrounds, to better reflect older people's views.

Abstract

Background:

Falls in older adults are expensive to the NHS and reduce quality of life for victims. Fear of falling (FoF) also increases the risk of falls. Virtual reality (VR) supported exposure treatments could potentially save labour and costs and can improve FoF, though few VR treatments have been co-productively designed.

Aims:

To evaluate perceived acceptability, tolerability and feasibility of a co-productively designed VR FoF exposure intervention in older adults. To also determine if patients are willing to participate in this intervention.

Methods:

Older people (≥ 65 years) with existing or previous FoF were recruited from NHS Psychology services. They received information on the intervention, involving exposure to feared scenarios. Participants engaged in semi-structured telephone interviews, providing feedback, including on perceived tolerability and acceptability. Measures of anxiety and low mood were also gathered. Interviews were analysed qualitatively via Braun & Clarke's (2006) thematic analysis.

Results:

There were 10 sub-themes within overarching themes. Additional comments emphasised fall experiences, physical health, motivation and effects of COVID-19 on exercise. Most reported high anxiety and FoF.

Conclusion:

Results suggested older people are mainly positive and willing to engage in VR for FoF. Most could envisage it as usual treatment. Implications include increased reassurance being required from clinicians and clear explanations of technology, more VR tasks outside the home and adaptations for health conditions.

Keywords: Virtual Reality; Fear; Falling; Psychology; Anxiety.

1. Introduction & Theory

1.1 Background

Approximately one third of over 65-year-olds fall annually (National Institute for Health and Care Excellence [NICE], 2013), with half of those 80 years or older at risk of falling (NICE, 2013). Falls can result in serious injuries, particularly fractures. They cost the NHS up to billions of pounds yearly for outpatients and inpatients, including in Scotland (Craig et al., 2013; McGinley et al., 2020; Public Health England [PHE], 2017; NICE, 2018), with emergency hospital admissions costing £2-billion (NICE, 2018) and social care following fractures costing £1-billion (PHE, 2017). Falls related to specific conditions, including glaucoma, have additionally been identified as costing millions (McGinley et al., 2020). This is also the case internationally, with California's annual cost alone being over £3-billion (Haddad et al., 2019).

Despite this, most people following falls are not seen by healthcare services (Graham & Firth, 1992), with 80% of non-injurious falls unreported to healthcare staff (Age Concern, 1997). This is concerning considering past falls can predict future falls (NICE, 2013). Risk factors are intrinsic or environmental (Todd & Skelton, 2004). Unsuitable lighting, walking aids or floor surfaces extrinsically increase falling risk (Dean & Ross, 1993; Lord et al., 2000). Intrinsic physical and mental health factors include arthritis, depression and stroke (NICE, 2013); multimorbidity further heightens risk (NICE, 2018)

1.2 Fear of Falling

Falls reduce quality of life (QoL), with effects including activity avoidance, frailty and reduced socialising (PHE, 2017; Arfken et al., 1994). With an ageing population, falls prevention is increasingly important to reduce NHS costs and

enhance wellbeing (McLean et al., 2015). Fear of falling (FoF) equally impacts QoL, limiting living activities (Suzuki et al., 2002). FoF is reduced confidence in balance abilities, often associated with reduced daily activities and exercise (Maki et al., 1991; Martin et al., 2005). It can develop whether people have fallen previously or not (PHE, 2017), and can increase falling risk via impaired balance ability (Li et al., 2003).

Young and Williams (2015) described psychological mechanisms behind this, drawing from Attentional Control Theory (Eysenck et al., 2007). These include increased anxiety, negatively altering attentional movement-related processes. Hence, people become preoccupied with threatening stimuli, irrelevant to movement tasks. They become distracted by anxious thoughts about falling, leaving inadequate attentional resources remaining to safely guide movement. This anxiety also reduces ability to retain visuospatial information in working memory, for example, where obstacles are (Young & Williams, 2015). Moreover, people stiffen their body to avoid falling, compromising ability during postural tasks with high working memory demands, like navigating uneven pavements (Young & Williams, 2015).

1.3 Interventions: Virtual Reality

Given the role of psychological processes, Cognitive Behavioural Therapy (CBT) elements have been successfully used, improving FoF, depression and QoL, with reasonable effect sizes for reducing FoF versus controls (*Cohen's d* = 0.4) (Parry et al., 2016; Liu et al., 2018). There is necessity for efficient replicability, improved costs and labour in psychological interventions (Freeman et al., 2018), as also found in the systematic review in Chapter one. Evidence suggests that interventions reducing falls in older adults can be cost-effective when there are reductions in medical care costs (McLean et al., 2015). Virtual Reality (VR) is increasingly used in psychological exposure interventions, addressing this. VR is defined as an interactive computer simulation whereby

users' physical actions are sensed and fed back to their senses (e.g. visual or haptic), so they become immersed in virtual worlds (Mihelj et al., 2014). It often involves users wearing goggles or a helmet ('Head Mounted Device' [HMD]) through which they view this world, which tracks where they are looking. They also use hand-held controllers which tracks where their hands are, allowing them to interact with virtual objects. Its advantages include ecological realism, low physical risk, experiencing situations impossible in reality and low logistical efforts once set up (Fromberger et al., 2018). Additionally, there is a need for reduced labour and costs in these psychological interventions; semi-automated technology like VR can help this. For example, one clinician could provide therapy for multiple people engaging in automated VR technology, thereby saving labour costs (Freeman et al., 2018).

A meta-analysis found VR exposure therapy as effective at improving anxiety disorders as in-vivo therapy, with a large effect size ($g = 0.9$) (Carl et al., 2019). Studies have demonstrated benefit for anxiety disorders using automated VR-treatment, conducive to replicable low-labour therapy (Freeman et al., 2018). VR FoF exposure therapy interventions have had success in reducing anxiety, demonstrating older adults tolerate associated HMDs (Levy et al., 2016). VR interventions are particularly successful when including both exposure to challenge FoF beliefs and interaction in environments to internalise new beliefs (Levy et al., 2016).

1.4 Co-production

Co-production of mental health interventions has been used less than in physical health (Larkin et al., 2015). It is increasingly considered crucial in developing psychological VR interventions. A seminal paper described three stages for VR healthcare studies to follow for best 'end-user' outcomes (Birckhead et al., 2019) (**Table 1**); end-users in this case are older people with FoF.

Table 1: VR healthcare research stages

Stage	Focus
VR1 ↓	Developing content to “promote empathy, team collaboration, and continuous user feedback”.
VR2 ↓	Exploring “early testing... feasibility, acceptability, tolerability, and initial clinical efficacy.”
VR3	Randomised controlled trials (RCTs).

(Birckhead et al., 2019).

‘Acceptability’ is patients’ willingness to use interventions, ‘Feasibility’ is the extent it can be effectively utilised in care and ‘Tolerability’ involves evaluating adverse effects, physical or emotional. Some CBT-based FoF treatments have co-designed interventions using patient interviews (Parry et al., 2016). However, few VR-based interventions have co-produced interventions, including RCT studies of FoF and phobias (Carl et al., 2019; Levy et al., 2016). Nonetheless, older people with FoF tolerate HMDs and experience improved anxiety (Levy et al., 2016).

This study combined Birckhead et al.’s (2019) VR1 and VR2 stages, remotely evaluating a FoF VR intervention, regarding participants’ perceived tolerability, feasibility and acceptability. Semi-structured interviews gathered rich qualitative data. A similar study assessed older people’s acceptance of a FoF VR exercise intervention via questionnaires (Mascret et al., 2020). However, this was less focused on psychological exposure and did not use interviews. This research step comes before participants test the intervention in-person, allowing further changes to be made to meet end-users’ needs. It was designed in line with the Medical Research Council’s (MRC) development process for complex interventions, helping develop interventions efficiently, minimising wasted efforts

(Craig et al., 2019). VR is not currently used to treat FoF in NHS settings, making this novel and beginning iterative processes of developing cost and labour-saving interventions in collaborative patient-centred ways.

1.5 Aims

To evaluate perceived acceptability, tolerability and feasibility of a VR intervention in older adults, designed to target psychological process related to FoF. Specifically:

- To determine perceived tolerability and acceptability of VR as a FoF treatment, gaining qualitative feedback
- To determine if FoF patients are willing to participate in a VR intervention

2. Methods

2.1 Participants

Older adults (≥ 65 years) who currently or have historically experienced FoF as diagnosed by Clinical Psychologists.

2.2 Inclusion Criteria

Currently or previously treated within NHSGGC older adult Psychology services and have/had FoF.

2.3 Exclusion Criteria

Never treated within older adult NHSGGC services or who have never had FoF. Any disorder undermining capacity to provide informed consent as determined by Clinical Psychologists.

2.4 Design

The design was qualitative, involving individual semi-structured telephone interviews about the intervention, analysed thematically. Participants did not engage in VR but received visual and written materials about it via post. Quantitative mental health measures were also collected and presented descriptively.

The recruiting Consultant Clinical Psychologist was consulted throughout intervention design. They proposed features based on clinical experience to be included, ensuring it was based on psychological theory. A FoF service-user of NHS Older Adult Psychology was also consulted on their experience and needs, prior to intervention design. Feedback was communicated to Computer Science colleagues at the University of Glasgow, who programmed the VR intervention, and elements were improved iteratively over multiple meetings. Ultimately there were two versions of the intervention, the second version being presented to participants. They were designed by Computer Science students, supervised by a Professor of Computer Science. The present primary researcher and their supervisor also contributed to intervention-development in these meetings. For instance, by shaping written instructions for participants around psychological exposure theory and proposing specific tasks and environments. The primary researcher also physically tried the full intervention to assess final quality and provide ongoing feedback to Computer Science colleagues. **(Appendix 2.3).**

2.5 Sample Size Justification

There is no definite answer to the ideal number of participants in qualitative research, being dependent on many practical issues (Baker & Edwards, 2012). Research examining older people's perspectives on FoF via interviews varied greatly in sample size, from under 10 to nearly 100 (McMahon et al., 2011). Generally, those with smaller samples collected "richer" data. The National Institute for Health Research (NIHR, 2017) suggested sample calculations are unnecessary for most qualitative research but indicate samples must be adequate to reach theme "saturation" and represent the target population. A co-production study gaining qualitative feedback for a VR psychosis intervention used 20 participants, via convenience sampling (Realpe et al., 2019). Guidelines on "small" thematic analyses suggest under 10 participants is feasible (Braun & Clarke, 2013). Data from the NHSGGC older adult psychology service suggested 14 referrals were directly FoF-related over the past year (March 2019-20). This somewhat limited the sample pool; such practical issues also inevitably affect sample sizes (Baker & Edwards, 2012). In addition to the short time-period available and early stages of this research, convenience sampling was used aiming to recruit five participants. This was adequate to determine preliminary data on feasibility, acceptability and tolerability. It was also deemed adequate to elicit relevant themes, based on past guidance (Baker & Edwards, 2012). Recruiters tracked numbers of patients approached versus those who participated.

3. Procedure

3.1 Recruitment

Two Clinical Psychologists based in Glasgow's NHS Older Adult Psychology service, one of whom was a Consultant, identified patients meeting inclusion criteria from their past/ present caseloads. These recruiters then contacted potential participants, gaining consent for the primary researcher to send

Participant Information Sheets (PIS) and then call to gain informed consent to participate.

3.2 Research Procedure

Written and visual materials on the intervention were posted to participants and a telephone call was scheduled. This comprised individual semi-structured interviews gaining qualitative data on perceived acceptability, feasibility and tolerability. Interviews occurred around a week after participants received the materials, to give them time to peruse them.

The call included firstly gathering demographic information, then conducting three mental health measures and finally the semi-structured interview on their views of the FoF intervention. Once completed, data were analysed qualitatively as described below.

3.3 Measures

Three validated self-report mental health measures were conducted within the interview call, including: Patient Health Questionnaire-9 (PHQ-9) (Kroenke et al., 2001); General Anxiety Disorder-7 (GAD-7) (Spitzer et al., 2006); Falls Self-Efficacy Scale (FES-I) (Tinetti et al., 1990) (**appendix 2.4**). These were gathered to help characterise the sample's mental health. All are regularly used as outcome measures in Glasgow Older Adult Psychology services, as recruiting Clinical Psychologists advised.

PHQ-9

This short self-report questionnaire assesses low mood, comprising nine questions scored on a four-point scale, including items on tiredness, concentration and hopelessness. Users answer based on symptoms over the past fortnight. It is

validated for screening depression in various populations, including older people (Gilbody et al., 2007). It is very reliable over the phone and in-person (intraclass correlation coefficient [ICC] = 0.9) (Pinto-Meza et al., 2005).

GAD-7

This brief self-report questionnaire assesses anxiety. It comprises seven items scored on a four-point scale, including worry, restlessness and irritability. Again, users answer based on symptoms over the past fortnight. It is reliable (ICC = 0.89) (Löwe et al., 2008) and validated, including for older people, with moderate to high sensitivity and specificity for anxiety disorders (Kroenke et al., 2007; Swinson, 2006).

FES-I

This self-report measure of FoF comprises 16 items, scored on a four-point scale. Users rate their falling concern in various situations, including stairs, dressing or navigating crowds. If they do not or cannot do the activity, they answer based on how they would feel if they did do it. In older people, it has good reliability (ICC = 0.96) (Yardley et al., 2005) and validity (Hauer et al., 2010).

3.4 Intervention Materials

Written and visual materials firstly described the aim of the intervention and then explain what VR is, including photos of equipment and how it is used. It outlined potential VR-induced symptoms and effects (VRISE), including motion-sickness. It then outlined the intervention, with images of menu screens (**Figure 1**), environments and how users interact with these. The tasks are set in various environments, including a kitchen, bedroom, living room and garden (**Figure 2**).

The tasks are graded from easier to harder, based on behaviours those with FoF might commonly find challenging, including bending down and navigating cluttered or darker environments. Images of users engaging in these tasks are depicted. One example is walking across a garden path to reach the post-box. Another is walking across a living room, around furniture, to retrieve a television remote (**Figure 3**). The virtual therapist or 'avatar' is also introduced, guiding users through the therapy with verbal prompts. Participants read about the anxiety Likert scales, completed before and after exposure to environments. This tracks users' self-reported FoF and thereby their recovery.

The 'tilt alarm' feature is also described, alerting users if they physically tilt too far forward whilst walking. This gives them opportunity to correct their posture and improve their balance. This was suggested by the consulting Clinical Psychologists to target this maladaptive FoF feature. Research also suggests that dynamic balance, during movement, may be related to FoF and falls (Maki, 1997). The alarm itself consisted of neutral beeping and users can turn off the feature by turning the volume down. (**Appendix 2.5**).



Figure 1: Example of main menu screen.



Figure 2: Example of garden task.



Figure 3: Example of living room task.

3.5 Semi-structured interview questions

Telephone interview questions were based on recommendations for exploring user-experience of VR via semi-structured interviews and on past research using these same methods (Birckhead et al., 2019; Jung et al., 2017).

Interviews started with exploring participants' General impressions, moving onto questions covering: Acceptability (e.g. "Are the tasks relevant to you?", "Would you be willing to try this intervention?"), Feasibility (e.g. "Can you see this being part of regular treatment for FoF?") and Tolerability (e.g. "What is your view on the VR induced symptoms and effects?"). 'Acceptability' in this case is defined as the degree to which participants consider the intervention to be appropriate (Sekhon et al., 2017). 'Feasibility' is how relevant and sustainable it is, including how participants perceive it as 'treatment as usual' for FoF, given they have undergone regular psychological therapy for FoF. 'Tolerability' is whether participants believe they can comfortably tolerate or endure the intervention.

As participants did not receive the intervention, but read and viewed information on it, their responses were based on anticipated cognitive and emotional responses. There was no interview time-limit and participants had opportunity to ask questions or freely comment on the materials. **(Appendix 2.6)**.

3.6 Ethical Approval

Ethics were approved by NHS Greater Glasgow and Clyde board of Research and Innovation in February 2021 (reference number: GN20MH679; Integrated Research Application System reference number: 287360). **(Appendices 2.7-8)**.

3.7 Data Analysis

Mental health measures were reported descriptively, adhering to recommendations on reporting studies concerning feasibility (Arain et al., 2010). Semi-structured interviews were audio-recorded, transcribed and analysed qualitatively via Braun & Clarke's (2006) thematic analysis. This was chosen as it is a flexible analysis which can be used with many qualitative questions, without having to prescribe to theoretical assumptions (Braun & Clarke, 2006), making it suitable for this exploratory research. The six steps were followed by the primary researcher, including: 1. Familiarisation with data, 2. Coding, 3. Generating initial themes, 4. Reviewing themes, 5. Defining/ naming themes, 6. Writing up. A deductive-inductive procedure was used; both approaches can be part of thematic analysis (Braun & Clarke, 2006). This involved both top-down and data-driven coding, therefore combining deduction and induction. This 'reflexive' approach is encouraged by recent thematic analysis research (Braun & Clarke, 2019b). This hybrid approach has also been used successfully in similar qualitative studies (Barraciff et al., 2018; Fereday & Muir-Cochrane, 2006).

The initial step involved deductively identifying topics of interest, based on existing knowledge. This was achieved by separating participants' interview answers by theme of the interview questions, such as issues of VR tolerability, including side-effects. As described, these questions were designed a priori based on previous research using similar methods and on recommendations for exploring VR user-experience via interviews (Birckhead et al., 2019; Jung et al., 2017). The next step was inductive, with further themes within these deductive categories emerging from the data, specifically, participants' interview answers.

At step four, themes were discussed with a second independent researcher (a Trainee Clinical Psychologist) to explore the data further (Moore et al., 2015) (**Appendix 2.9**). As Braun and Clarke's (2006) approach advocates against use of inter-rater reliability measures for thematic analysis, this was conducted only to invigorate thinking and increase data-immersion (Braun & Clarke, 2019b). This works within their ethos that there is no single 'right way' to code data, positing that coding is an *“active and reflexive process that inevitably and inescapably bears the mark of the researcher”*; thus removing the need for independent multiple coders in thematic analysis (Braun & Clarke, 2019a).

4. Results

4.1 Recruitment & demographics

The recruiting Psychologists approached 11 eligible people to potentially participate. Nine of these 11 (82%) consented to be contacted by the primary researcher and two declined. Of those then contacted by the primary researcher, two more declined, one did not respond and one was unable to receive materials required for interview, though they consented to participate. Nonetheless, they provided demographic information and completed mental health measures.

A total of five participants completed both the mental health measures and interview. Overall, six out of 11 (55%) of those initially approached consented to engage.

Table 2 presents demographic characteristics. All six participants were retired females, with an average age of 74 years (SD = 5.2). Participant '5' is the person who was unable to complete the interview, as described previously. All were from similar ethnic backgrounds, white Scottish, and had 'low-skilled' type jobs pre-retirement. Most left school in their mid to late teens. Scottish Index of Multiple Deprivation (SIMD) data were collected from participants' current postcodes. This relative measure of deprivation across Scotland is based on employment, health, education and other factors. Four participants (67%) were in the least deprived decile and two (33%) lived in more deprived areas.

Table 2: Demographic characteristics

Participant	Age	Gender	Ethnic Identity	SIMD Category	Past Occupation	Education-level
1	65-70	Female	White Scottish	10% least deprived	Administrator	Secondary school- Until 16 years
2	75-80	Female	White	10% least deprived	Administrator. Driver	Higher education- College
3	75-80	Female	Scottish	10% most deprived	Administrator	Secondary school- Until 15 years
4	65-70	Female	Scottish	10% least deprived	Administrator. Shop assistant	Higher education- College
5	75-80	Female	Scottish	30% most deprived	Charity worker	Unsure
6	75-80	Female	Scottish- Jewish	10% least deprived	Salesperson	Secondary school- Until 15 years

Scottish Index of Multiple Deprivation (SIMD) percentages of most to least deprived areas for participants' current addresses.

4.2 Measures

Table 3 outlines mental health scores. All participants completed all questionnaires. Scores ranged from 'Normal' to 'Severe anxiety' on the GAD-7, with the average indicating 'Moderate anxiety' (M = 11, SD = 6.1, Range = 1–19). The commonest was 'Severe anxiety' (50%). Mood measure, PHQ-9, scores ranged from 'Normal' to 'Severe low mood' (M = 10, SD = 5.8, Range = 4-20), with the commonest scores indicating 'Mild' (33%) or 'Moderately-severe' (33%) low mood. One statement participants rate is "Thoughts that you would

be better off dead or of hurting yourself". No participants reported thoughts of this nature, nor plans or intent to act on them. FES-I scores for FoF were generally high; the average score specified 'High' falling concern (M = 38, SD = 7.3, Range = 23-45). Scores indicating 'High' falling concern were the commonest (83%).

Table 3: Mental health measures

Participant	GAD-7 Score /21	GAD-7 Interpretation	PHQ-9 Score /27	PHQ-9 Interpretation	FES-I Score /64	FES-I Interpretation
1	6	Moderate Anxiety	5	Mild Low Mood	41	High Falling Concern
2	9	Moderate Anxiety	5	Mild Low Mood	41	High Falling Concern
3	19	Severe Anxiety	20	Severe Low Mood	45	High Falling Concern
4	15	Severe Anxiety	12	Moderately-Severe Low Mood	36	High Falling Concern
5	15	Severe Anxiety	13	Moderately-severe Low Mood	43	High Falling Concern
6	1	Normal Anxiety	4	Normal Mood	23	Moderate Falling Concern
Mean	11	Moderately-severe Anxiety	10	Normal	38	High Falling Concern
Median	12	Moderately-severe Anxiety	9	Normal	41	High Falling Concern

Cut-off points:- GAD-7: 0-5= Normal anxiety, 6-10= Moderate, 11-15= Moderately-severe, 15-21= Severe. PHQ-9: 0-5= Normal mood, 6-10= Moderate, 11-15= Moderately-severe, 16-27= Severe. FES-I: 16-19= Low falling concern, 20-27= Moderate, 28-64= High.

4.3 Thematic Analysis

Semi-structured interviews, excluding time taken for mental health measures and demographics collection, ranged from 8 minutes (m) 4 seconds (s) to 20m 59s (M= 14m25s, Median= 15m52s, SD= 4m45s). As outlined, questions comprised four overarching themes in line with research aims, including: General impressions, Acceptability, Feasibility and Tolerability. Within participants' answers to these were 10 sub-themes (**Table 4**), alongside example quotations. Some sub-themes appeared across multiple question themes.

Table 4: Themes and sub-themes

Question Theme	Sub-theme (no. participants expressing theme)	Example Quotations
General Impressions	Certainty & safeness (5)	<p>“I know you’d be in a safe environment. That you wouldn’t fall or be hurt. You’d put your trust in that therapy.” (P2)</p> <p>“...it’s all helpful and useful for someone who needs help.” (P4)</p>
	Technological understanding & experiences (4)	<p>“...you might need to be a little aware of the technology and be alert and understanding about it.” (P1)</p> <p>“We had been at my daughter’s one evening and we try trying them (VR) out and we were on a rollercoaster.” (P5)</p>
	Physical ability & health (4)	<p>“...my hands don’t work very well. The Parkinson’s takes over when I try to do things. Sometimes you can’t do what you’d like to do because they’re not steady enough.” (P3)</p>
	Engagement & trust (5)	<p>“I know you’d be able to see from my expression and any noise I made that I wasn’t happy.” (P2)</p>

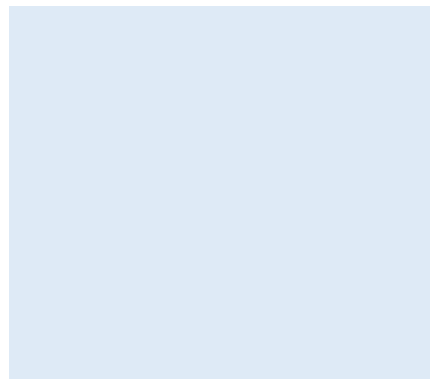
	<p>“It will take them time I think for people to get adjusted to it. But it may well help...” (P5)</p>
<p>Fall experiences (4)</p>	<p>“Sometimes if I try and look up from my feet, I fall backwards rather than forwards. I try to push myself up, as I can’t pull myself up.” (P3)</p> <p>“...recently in January with the ice. I’ve had a hard fall. It’s just outside my backdoor steps. It was at 11pm at night. Husband was in his bed- I could have laid there all night.” (P1)</p>
<p>Task relevance, choice & difficulty (5)</p>	<p>“To me they were common sense, everyday tasks that you would. See opening the cupboard, it’s something you would do every day. And walking out your front door. Tasks they would all encounter” (P2)</p> <p>“Very much so. Particularly the walking and the avoiding obstacles on the ground... picking up a mobile phone.” (P5)</p> <p>“I didn’t think the obstacles were too difficult to do.” (P5)</p> <p>“Yes I think so [that tasks are graded appropriately]. The walking and then with the obstacles later on.” (P1)</p>

Acceptability	Task relevance, choice & difficulty (5)	<p>“Initially I thought it was a wonderful idea but now I think maybe people experiencing these different challenges would have been better having a set of stairs in the real world...” (P5)</p> <p>“How much it would help someone in the real world I don’t know.” (P5)</p>
	Technological understanding & experiences (4)	<p>“I’m not very steady at all when I do things like that.... If I’m using the controllers, I’d be saying to myself, I’m not holding onto something here” (P3)</p> <p>“I like my laptop, I’m into my... technology. And I’ve tried the virtual reality before” (P5)</p>
	FoF improvement (3)	<p>“Just to see the delight of having something that works” (P3)</p> <p>“Yes. Because it’s only going to help me” (P2)</p>
	Certainty & safeness (5)	<p>“No, no I don’t think so (no uncertainty about trying)” (P1)</p> <p>“I would try it” (P3)</p>
	Physical ability & health (4)	<p>“... (depends) whether you were physically or mentally mobile.” (P1)</p> <p>“I can only do these things at a certain pace, for so long. And then I start to feel myself go off” (P3)</p>

	Other health treatments (2)	“I’m doing hypnosis, so it’s helping. I’ve got to do the hypnosis. I’ve got so many homeworks to do, I’ve got it from them and you and from my OT and from all these people. I say I don’t have time” (P4)
Feasibility	Fall experiences (4)	“Yes I think it would (meet needs), but recently I’ve been getting better. I’ve improved a lot since I fell and fractured my shoulder. But I am very wary on ladders or stools.” (P1)
	Task relevance, choice & difficulty (5)	“Yes, (could also include) stairs. If your balance isn’t good and you’re manoeuvring stairs, in and outside.” (P1) “ going down a hill...That’s just my fear of hills. You’re doing this for a wide range of people who’ve fallen- maybe not all of them have a fear of hills.” (P2)
	VR as treatment as usual (TAU) (5)	“Yes I think it would be a good idea. It gives people a chance to do it virtually rather than from a physio point of view” (P1) “Yes I definitely think it should be introduced into the NHS to help people.” (P2)
Tolerability	Side-effects (5)	“...when that headsets on, you’re very unbalanced. I was when I put it on. Very unbalanced.” (P5)

	<p>“Yes I think it would (put me off). Because I’ve just got rid of vertigo.” (P4)</p> <p>“Might make people feel too closed in when you have something on your head like that. So people sort of panic a bit. I think that can cause you to feel worse than what you would normally.” (P3)</p>
<p>Engagement & trust</p> <p>(5)</p>	<p>“I’d put my faith and trust in the clinician...” (P2)</p>
<p>Task relevance, choice & difficulty</p> <p>(5)</p>	<p>“I think doing it from the easy part and working up to harder most difficult part- I think that would be good. By the time you got onto the difficult part you’d be more able.” (P1)</p>

With example quotations from participants (P).



Certainty & safeness

This theme covered certainty about the treatment, feeling assured and safe. It was frequently conveyed by all participants in short definite answers. For instance, having an impression of:

“Excellent. Very very good.” (P2)

Or regarding VR realism:

“Oh yes. They did (look realistic). Oh yes. They did.” (P5).

Other statements described usefulness of the treatment for tackling FoF and safety they felt with it being led by clinicians, reducing uncertainty:

“...you’d be in a safe environment” (P2).

Technological understanding & experiences

This was defined as answers referring to past experiences with, or understanding of, technology and VR. One patient tried VR before and others referred to generational differences:

“...young people are used to putting these things (VR headsets) on, older people may be more suspicious.” (P5).

There was a sense that participants had to be more aware when interacting with technology. One participant used incorrect terms for instance, describing the HMD as a “camera” (P5). Another did not fully understand the tilt alarm concept after explanation, initially referring to personal alarm buttons:

“I’ve got an alarm on my wrist. When you press the button and the person comes out. I find it useful.” (P4)

Physical ability & health

This covered references to physical health, often injuries or conditions, and ability to physically engage. Notably, some were in wheelchairs or fatigued just talking during interviews. One reported Parkinson's Disease being an issue if using VR controllers. Another asked:

“Do you have an option to sit down?” (P2)

This was apparently relating to physical ability and FoF. This sub-theme reflects most older people having health conditions and multimorbidity, which increases falling risk (NICE, 2018).

Engagement & trust

This encompassed participants' willingness to engage, which was related to their trust in the treatment. This differed from 'Certainty & safeness' as these statements were less certain and assured- often tentative expressions around engagement. Some believed it would take time to engage and acclimatise. Others mentioned having no choice but to trust clinicians. Participants often mentioned inherent disposition and motivation of end-users as being an engagement factor:

“Depends on the person. Some people are positive and some are negative...” (P3).

Fall experiences

This theme comprised explicit experiences of past falls, sometimes related to subsequent FoF; experiences were described in detail when raised. This included one participant reporting two frightening fall events, including on ice and when putting the rubbish out. Another mentioned multiple falls as a younger adult. Resulting injuries were also discussed:

“When I fractured my shoulder, it was in the kitchen. I tripped over my dog.” (P1).

Task relevance, choice & difficulty

This covered relevance of VR treatment to everyday life, including visual realism and the nature of completing tasks, including choice and difficulty. All participants related well to visual aspects, finding rooms and tasks relevant and recognisable. They reported variety and sense of choice. Tasks were also similar to their own daily chores, described as:

“common sense, everyday tasks... they would all encounter” (P5).

One participant noted that tasks were not too challenging, whilst another found the cluttered garden unnerving. It was also pertinently stated that there were no tasks in public:

“...people go to shopping malls and what have they got from one level to the next (on) an escalator” (P5).

Others also explained that hills and steps would be useful additions, as FoF triggers. Overall, participants understood psychological exposure theory behind the tasks:

“By the time you got onto the difficult part you’d be more able” (P1).

FoF improvement

This theme comprised answers discussing FoF improvement, relating to potential treatment effects. Most were positive about the treatment reducing FoF, feeling it would be good to at least try. One person pragmatically stated:

“I would have had to have tried it to really be able to say, yes this going to work for me. Everybody’s different.” (P5).

Some mentioned they wished it were available when they had their psychological treatment. The underlying view was that something is better than nothing:

“it’s only going to help me” (P2)

Some were even more positive in their language:

“...delight of having something that works” (P3).

Other health treatments

A minority mentioned other FoF treatments, but were clear in their comparison to VR treatment. Hypnosis and Occupational Therapy for FoF was discussed by one. She framed these as barriers for engaging, due to time constraints:

“I’ve got so many homeworks to do” (P4).

Another participant outlined VR as an alternative to physical exercises for FoF. Past psychological support was expressed as useful, though most still valued VR treatment as an approach which could further help them.

VR as treatment as usual (TAU)

This covered statements about VR FoF treatment being TAU, including in the NHS. All participants thought it would work well as TAU, at the least feeling that:

“I don’t think it would be any harm to people who need it really.” (P4).

One person expressed:

“I definitely think it should be introduced into the NHS” (P2).

It was clear that many felt they would like to try it to reduce FoF, which had persisted for some despite treatment:

“I ended up going to the Psychologist. In a way it’s still with me, the fears are still there. But I’m careful.” (P5).

Side-effects

‘Side-effects’ comprised concerns around physical and mental VR-induced side-effects. One mentioned existing vertigo as an engagement barrier, fearing it would worsen. Another who had tried VR reported she felt *“very unbalanced”* (P5), whilst another who had not tried it speculated people may feel *“closed in”* (P3). It did not entirely deter participants, as they were comforted by the temporary nature of them:

“any dizziness you felt would pass” (P2)

Overall, most expressed interest despite knowledge of side-effects.

Other comments

Participants were given opportunity to make further comments without question prompts, unlike previous sub-themes. Three of the five participants did so. One participant explained:

“I do have underlying medical things going on. I don’t know if some of my thoughts and feelings are connected (to the VR treatment) because of this.” (P2).

This implies that her medical issues are related to her perception of the treatment. This also mirrors sub-theme “Physical ability & health”, in which participants discuss how physical issues might inhibit their VR participation.

Another participant emphasised:

“There’s always been falling in my life.” (P5)

She disclosed:

“...my first fall downstairs when I was 16 years of age” (P5).

“When I was pregnant with my first child, I fell down the stairs” (P5).

This suggests her FoF may have developed pre-old age. She further discussed suggested inclusion of escalators, as outlined in “Task relevance, choice & difficulty”. She had fears of these, favouring lifts instead.

One participant described effects of COVID-19 on her physical activity and motivation:

“Before Covid- I attended an aqua Zumba class. Also I did an aerobic class... I did all these things despite my age. I was active...it’s important that people want to have the confidence to improve... rather than give up.” (P1).

This related to the physical motivation to engage in a novel VR intervention. She added:

“I’ve had breast cancer this past year as well- I had two operations and had Covid for 12 days. And I had the radiotherapy. But I’m bouncing back to my normal self. I’m confident I’ll get back to normal once my classes start again”. (P1).

Her drive to overcome health barriers, and the benefit of physical group interventions, was reflected by this. This personal motivation is important for

success in VR interventions according to participants, as noted in 'Engagement & trust' sub-theme:

“Depends on the person. Some people are positive and some are negative about things.” (P3).

5. Discussion

5.1 Main findings

This study evaluated perceived acceptability, tolerability and feasibility of a VR intervention targeting FoF in older people. It combined Birckhead et al.'s (2019) stages of co-productive VR design, allowing changes to be made based on the present feedback, meeting end-users' needs.

Within overarching question themes, there were 10 sub-themes including: 'Certainty & safeness', 'Technological understanding & experiences', 'Physical ability & health', 'Engagement & trust', 'Fall experiences', 'Task relevance, choice & difficulty', 'FoF improvement', 'Other health treatments', 'VR as TAU' and 'Side-effects'. Other comments emphasised physical health, early-life fall experiences, motivation and effects of COVID-19 on exercise groups and mobility.

Whilst these sub-themes were identified, answers often spanned multiple sub-themes, linked by overarching question themes. This demonstrates that aspects of acceptability, feasibility and tolerability overlap, implying that similar issues are important to older adults across domains in their views of the treatment.

Previous research supports sub-themes relating to VR 'usability', including 'Technological understanding & experiences', 'Task relevance, choice & difficulty' and 'VR as TAU'. One study suggested mastering hand controllers is key for 'useable' and autonomous VR in older people (Baker et al., 2020). One participant noted concern regarding this due to Parkinson's Disease; alternatives have been suggested, including haptic gloves (Baker et al., 2020). Parkinson's sufferers also experience worse FoF than controls (Nilsson et al., 2012); more disabling Parkinson's symptoms, including shuffling, additionally correlate with worse FoF (Rahman et al., 2011).

Understanding and acclimatising to technology was important to participants, as in sub-theme 'Technological understanding & experiences', with only one participant using VR before. Another misunderstood the tilt alarm, referring to personal alarm buttons. Given past research suggests older adults are accepting of HMDs (Lin et al., 2018), these findings suggest they are not averse to participating, but need concerns assuaged, requiring detailed explanations. Therefore, clinicians directing VR treatments must thoroughly explain technological aspects to address this need.

Most were willing to engage and felt others would be also. This was apparent in 'Certainty and safeness' and 'FoF improvement' sub-themes. They felt that tasks in their realism, relevance to everyday life and choice, were appropriate with suggestions for adaptations. These included options to sit down and public tasks, including escalators. Although outdoor tasks were included, the lack of public settings might reflect the psychology researchers' assumptions that FoF patients do not frequently leave home. This is not true for all older people, with choices to go shopping for example shaped by factors in addition to FoF. These include weather, travel costs and health conditions (Bezirgani & Lachapelle, 2021). One participant noted falls in earlier life as a factor developing FoF. This was notable, as although past falls can predict future falls, these are usually older-age falls (NICE, 2013).

Barriers to perceived engagement included VR side-effects, other health treatments, time constraints and physical health. Although visual acuity issues were unreported, this is common in older people and could interfere with engagement; it has been suggested that participants are asked about this, ensuring they are suitable for VR (Brown, 2019). However, visual issues themselves, including glaucoma, contribute to both falls and FoF (Daga et al., 2017; McGinley et al., 2020); meaning VR exposure would not necessarily aid FoF in these cases anyway. Nevertheless, most expressed willingness to try, with hopes of improving FoF and were happy to trust clinicians. This is bolstered by other research on older people, who enjoyed and accepted VR (Brown, 2019; Lin et al., 2018; Mascret et al., 2020). Although analysis suggests participants viewed the intervention generally positively, they did not engage in VR. Therefore, feedback was somewhat speculative, especially as few had tried VR before; nonetheless, it is important for determining initial engagement. Previous research has also successfully used this approach, remotely assessing participants' initial acceptance of falls VR exercise interventions. They found older people with less fall-related confidence perceived VR HMDs as more useful, albeit it was questionnaire-based without interviews (Mascret et al., 2020). However, it seems that positive attitudes, apparent in the present data, strengthen associations between intention and behaviour regarding technological engagement (Bhattacharjee & Sandford, 2009). This suggests many of this sample would likely participate in VR treatment if offered.

Participants reported moderately-severe anxiety and high falling concern on average, which makes sense given everyone experienced FoF. Anxiety was captured in sub-themes, but always linked to FoF or physical abilities. Half scored moderately-severe to severe low mood, with the remaining scoring normal to mild; though they reported normal mood on average. This supports previous research which suggests anxiety and depression are often present in, and associated with, FoF in older adults (Gagnon, 2005). Moreover, treating low mood and general anxiety may be crucial to also reducing their FoF (Gagnon,

2005). These scores emphasise need for support from clinicians for overall mental health, not just FoF, if this treatment comprised TAU.

Most participants fell into the least deprived SIMD decile and previously held 'low-skilled' jobs. There have been suggestions that poorer neighbourhood conditions might be linked to FoF, as falls on streets are likelier to result in injury, including dilapidated pavements (Curl et al., 2020; Li et al., 2014). Discomfort with neighbourhood environment is associated with higher FoF (Lee et al., 2018). Relatedly, fears of slopes outside their home were mentioned by one participant. However, FoF was also reported by some in usually well-kept areas like shopping centres. As there were participants in greater and lesser deprived SIMD deciles, the views on VR cover multiple socioeconomic perspectives. All participants were women, which reflects that being female is associated with higher FoF than being male (Lee et al., 2018); they are therefore likelier to be referred to mental health services for this.

The context of COVID-19 impacted some participants' physical functioning and enjoyable activities. One mentioned cessation of aerobic classes which she reported helped her confidence and motivation. Previous research supports this, finding that older people in lockdown experienced decreased exercise (Morley, 2020). Moreover, COVID-19 or similar illnesses, which some reported, can lead to increased bedrest and muscle tone loss- which increases falls risk (Morley, 2020). This contributes to the sense of hesitation in sub-themes concerning participants' ability to physically engage in VR, without becoming fatigued. Such concerns were commoner as barriers than the prospect of facing their fears in VR. Likewise, trusting clinicians when trying the treatment, was more important than understanding the graded exposure approach itself.

5.2 Limitations & future research

This study helped elucidate older people's views on acceptability, tolerability and feasibility of a FoF VR intervention. It co-productively involved end-users, allowing adaptations in content and application to be made to meet their needs. Collaboration between Psychology researchers and Computer Science colleagues to develop this is a strength. Interdisciplinary working is key for developing efficacious VR treatments, particularly when introducing technology to older generations, which must be done with clarity and patience, as findings suggest. The modest sample size suited this exploratory study, however larger studies involving more diverse perspectives is required- including men, non-white ethnicities and lower socioeconomic statuses, particularly as technology is less affordable to them, limiting their existing experience. Aside from the data suggesting willingness to participate, the ratio of participants approached versus those who participated gives initial indication of this too. Recruitment involved those who had already engaged with Psychology services, which may have introduced potential bias, given they may report higher willingness to engage than other older people would. Larger samples, including those who have not had previous FoF therapy, would further clarify engagement. Participants also did not receive the intervention; interviews were based on anticipated responses to VR- although this approach has been used successfully in past research. Since findings suggests older people are open to participating in this treatment, next steps would be to assess the elements of acceptability, tolerability and feasibility in-vivo, using VR HMDs.

Before assessing these elements in VR intervention development (Birckhead et al., 2019), participants' concerns must first be addressed. These include increased reassurance, technological explanations and adaptations for fatigue or health conditions and safe clinician relationships. Tasks were well received and relevant to participants, although a need for tasks in public was emphasised. Findings also inform future recruitment strategies. Recruiting using clinicians participants were treated by was successful and introductory written materials helped reassure and inform people further, before engaging in VR.

6. Conclusion

Results suggest older people are generally positive and willing to engage in VR for FoF, driven by desire to overcome past fall experiences. Most envisaged it as TAU. Despite this, adaptations to VR tasks should be made, suiting participants' needs. Care must be taken when introducing technology to older generations, accounting for higher rates of physical comorbidities, which can leave them fatigued. Alternatives to controllers might be considered for conditions like Parkinson's, including haptic gloves. Participants valued task choices and the graded exposure concept. After psychological treatment, many scored high for FoF, depression and anxiety, demonstrating the need for novel solutions. It also highlights requirement for multiple or longer FoF scales for measuring nuanced treatment responses, like the Activities-specific Balance Confidence Scale (Powell & Myers, 1995), which are sometimes avoided due to time limitations (Perez-Jara et al., 2010). Acceptability has been demonstrated in this modest sample; participants were willing to trust clinicians and tolerate potential side-effects. As older people also experience comorbidities, fitting this novel treatment around existing health treatments is researchers' responsibility and the next step in feasibility.

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Systematic Review Appendices (Chapter 1)

Appendix 1.1 – 10 - Manuscript Submission Guidelines: “Journal of Computers in Human Behavior”. (<https://www.elsevier.com/journals/computers-in-human-behavior/0747-5632/guide-for-authors>)

This write-up is transferable to the guidelines of the target journal. Some minor elements differ, for instance, their recommended ‘Introduction’ and ‘Theory’ sections are conflated, allowing readers to smoothly follow the project as a thesis.

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- Supply files that are too low in resolution.
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Van der Geer, J., Hanraads, J. A. J., & Lupton, R. A. (2018). The art of writing a scientific article. *Heliyon*, 19, Article e00205. <https://doi.org/10.1016/j.heliyon.2018.e00205>.

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Reference to a chapter in an edited book:

Mettam, G. R., & Adams, L. B. (2009). How to prepare an electronic version of your article. In B. S. Jones, & R. Z. Smith (Eds.), *Introduction to the electronic age* (pp. 281–304). E-Publishing Inc.

Reference to a website:

Powertech Systems. (2015). *Lithium-ion vs lead-acid cost analysis*. Retrieved from <http://www.powertechsystems.eu/home/tech-corner/lithium-ion-vs-lead-acid-cost-analysis/>. Accessed January 6, 2016

Reference to a dataset:

[dataset] Oguro, M., Imahiro, S., Saito, S., & Nakashizuka, T. (2015). *Mortality data for Japanese oak wilt disease and surrounding forest compositions*. Mendeley Data, v1. <https://doi.org/10.17632/xwj98nb39r.1>.

Reference to a conference paper or poster presentation:

Engle, E.K., Cash, T.F., & Jarry, J.L. (2009, November). *The Body Image Behaviours Inventory-3: Development and validation of the Body Image Compulsive Actions and Body Image Avoidance Scales*. Poster session presentation at the meeting of the Association for Behavioural and Cognitive Therapies, New York, NY.

Reference to software:

Coon, E., Berndt, M., Jan, A., Svyatsky, D., Atchley, A., Kikinon, E., Harp, D., Manzini, G., Shelef, E., Lipnikov, K., Garimella, R., Xu, C., Moulton, D., Karra, S., Painter, S., Jafarov, E., & Molins, S. (2020, March 25). *Advanced Terrestrial Simulator (ATS) v0.88 (Version 0.88)*. Zenodo. <https://doi.org/10.5281/zenodo.3727209>.

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Appendix 1.2 – Quality Assessment Tool

INTRODUCTION

JBI is an international research organisation based in the Faculty of Health and Medical Sciences at the University of Adelaide, South Australia. JBI develops and delivers unique evidence-based information, software, education and training designed to improve healthcare practice and health outcomes. With over 70 Collaborating Entities, servicing over 90 countries, JBI is a recognised global leader in evidence-based healthcare.

JBI Systematic Reviews

The core of evidence synthesis is the systematic review of literature of a particular intervention, condition or issue. The systematic review is essentially an analysis of the available literature (that is, evidence) and a judgment of the effectiveness or otherwise of a practice, involving a series of complex steps. JBI takes a particular view on what counts as evidence and the methods utilised to synthesise those different types of evidence. In line with this broader view of evidence, JBI has developed theories, methodologies and rigorous processes for the critical appraisal and synthesis of these diverse forms of evidence in order to aid in clinical decision-making in healthcare. There now exists JBI guidance for conducting reviews of effectiveness research, qualitative research, prevalence/incidence, etiology/risk, economic evaluations, text/opinion, diagnostic test accuracy, mixed-methods, umbrella reviews and scoping reviews. Further information regarding JBI systematic reviews can be found in the [JBI Evidence Synthesis Manual](#).

JBI Critical Appraisal Tools

All systematic reviews incorporate a process of critique or appraisal of the research evidence. The purpose of this appraisal is to assess the methodological quality of a study and to determine the extent to which a study has addressed the possibility of bias in its design, conduct and analysis. All papers selected for inclusion in the systematic review (that is – those that meet the inclusion criteria described in the protocol) need to be subjected to rigorous appraisal by two critical appraisers. The results of this appraisal can then be used to inform synthesis and interpretation of the results of the study. JBI Critical appraisal tools have been developed by the JBI and collaborators and approved by the JBI Scientific Committee following extensive peer review. Although designed for use in systematic reviews, JBI critical appraisal tools can also be used when creating Critically Appraised Topics (CAT), in journal clubs and as an educational tool.

JBI CRITICAL APPRAISAL CHECKLIST FOR QUASI-EXPERIMENTAL STUDIES

Reviewer _____ Date _____

Author _____ Year _____ Record Number _____

	Yes	No	Unclear	Not applicable
1. Is it clear in the study what is the 'cause' and what is the 'effect' (i.e. there is no confusion about which variable comes first)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Were the participants included in any comparisons similar?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Were the participants included in any comparisons receiving similar treatment/care, other than the exposure or intervention of interest?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Was there a control group?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Were there multiple measurements of the outcome both pre and post the intervention/exposure?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Were the outcomes of participants included in any comparisons measured in the same way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Were outcomes measured in a reliable way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Was appropriate statistical analysis used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Overall appraisal: Include Exclude Seek further info

Comments (Including reason for exclusion)

EXPLANATION FOR THE CRITICAL APPRAISAL TOOL FOR QUASI-EXPERIMENTAL STUDIES

How to cite: Tufanaru C, Munn Z, Aromataris E, Campbell J, Hopp L. Chapter 3: Systematic reviews of effectiveness. In: Aromataris E, Munn Z (Editors). JBI Manual for Evidence Synthesis. JBI, 2020. Available from <https://synthesismanual.jbi.global>

Critical Appraisal Tool for Quasi-Experimental Studies (Experimental Studies without random allocation)

Answers: Yes, No, Unclear or Not/Applicable

1. Is it clear in the study what is the 'cause' and what is the 'effect' (i.e. there is no confusion about which variable comes first)?

Ambiguity with regards to the temporal relationship of variables constitutes a threat to the internal validity of a study exploring causal relationships. The 'cause' (the independent variable, that is, the treatment or intervention of interest) should occur in time before the explored 'effect' (the dependent variable, which is the effect or outcome of interest). Check if it is clear which variable is manipulated as a potential cause. Check if it is clear which variable is measured as the effect of the potential cause. Is it clear that the 'cause' was manipulated before the occurrence of the 'effect'?

2. Were the participants included in any comparisons similar?

The differences between participants included in compared groups constitute a threat to the internal validity of a study exploring causal relationships. If there are differences between participants included in compared groups there is a risk of selection bias. If there are differences between participants included in the compared groups maybe the 'effect' cannot be attributed to the potential 'cause', as maybe it is plausible that the 'effect' may be explained by the differences between participants, that is, by selection bias. Check the characteristics reported for participants. Are the participants from the compared groups similar with regards to the characteristics that may explain the effect even in the absence of the 'cause', for example, age, severity of the disease, stage of the disease, co-existing conditions and so on? [NOTE: In one single group pre-test/post-test studies where the patients are the same (the same one group) in any pre-post comparisons, the answer to this question should be 'yes.']

3. Were the participants included in any comparisons receiving similar treatment/care, other than the exposure or intervention of interest?

In order to attribute the 'effect' to the 'cause' (the exposure or intervention of interest), assuming that there is no selection bias, there should be no other difference between the groups in terms of treatments or care received, other than the manipulated 'cause' (the intervention of interest). If there are other exposures or treatments occurring in the same time with the 'cause', other than the intervention of interest, then potentially the 'effect' cannot be attributed to the intervention of interest, as it is plausible that the 'effect' may be explained by other exposures or treatments, other than the intervention of interest, occurring in the same time with the intervention of interest. Check the reported exposures or interventions received by the compared groups. Are there other exposures or treatments occurring in the same time with the intervention of interest? Is it plausible that the 'effect' may be explained by other exposures or treatments occurring in the same time with the intervention of interest?

4. Was there a control group?

Control groups offer the conditions to explore what would have happened with groups exposed to other different treatments, other than to the potential 'cause' (the intervention of interest). The comparison of the treated group (the group exposed to the examined 'cause', that is, the group receiving the intervention of interest) with such other groups strengthens the examination of the causal plausibility. The validity of

causal inferences is strengthened in studies with at least one independent control group compared to studies without an independent control group. Check if there are independent, separate groups, used as control groups in the study. [Note: The control group should be an independent, separate control group, not the pre-test group in a single group pre-test post-test design.]

5. Were there multiple measurements of the outcome both pre and post the intervention/exposure?

In order to show that there is a change in the outcome (the 'effect') as a result of the intervention/treatment (the 'cause') it is necessary to compare the results of measurement before and after the intervention/treatment. If there is no measurement before the treatment and only measurement after the treatment is available it is not known if there is a change after the treatment compared to before the treatment. If multiple measurements are collected before the intervention/treatment is implemented then it is possible to explore the plausibility of alternative explanations other than the proposed 'cause' (the intervention of interest) for the observed 'effect', such as the naturally occurring changes in the absence of the 'cause', and changes of high (or low) scores towards less extreme values even in the absence of the 'cause' (sometimes called regression to the mean). If multiple measurements are collected after the intervention/treatment is implemented it is possible to explore the changes of the 'effect' in time in each group and to compare these changes across the groups. Check if measurements were collected before the intervention of interest was implemented. Were there multiple pre-test measurements? Check if measurements were collected after the intervention of interest was implemented. Were there multiple post-test measurements?

6. Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed?

If there are differences with regards to the loss to follow up between the compared groups these differences represent a threat to the internal validity of a study exploring causal effects as these differences may provide a plausible alternative explanation for the observed 'effect' even in the absence of the 'cause' (the treatment or exposure of interest). Check if there were differences with regards to the loss to follow up between the compared groups. If follow up was incomplete (that is, there is incomplete information on all participants), examine the reported details about the strategies used in order to address incomplete follow up, such as descriptions of loss to follow up (absolute numbers; proportions; reasons for loss to follow up; patterns of loss to follow up) and impact analyses (the analyses of the impact of loss to follow up on results). Was there a description of the incomplete follow up (number of participants and the specific reasons for loss to follow up)? If there are differences between groups with regards to the loss to follow up, was there an analysis of patterns of loss to follow up? If there are differences between the groups with regards to the loss to follow up, was there an analysis of the impact of the loss to follow up on the results?

7. Were the outcomes of participants included in any comparisons measured in the same way?

If the outcome (the 'effect') is not measured in the same way in the compared groups there is a threat to the internal validity of a study exploring a causal relationship as the differences in outcome measurements may be confused with an effect of the treatment or intervention of interest (the 'cause'). Check if the outcomes were measured in the same way. Same instrument or scale used? Same measurement timing? Same measurement procedures and instructions?

8. Were outcomes measured in a reliable way?

Unreliability of outcome measurements is one threat that weakens the validity of inferences about the statistical relationship between the 'cause' and the 'effect' estimated in a study exploring causal effects. Unreliability of outcome measurements is one of different plausible explanations for errors of statistical inference with regards to the existence and the magnitude of the effect determined by the treatment ('cause'). Check the details about the reliability of measurement such as the number of raters, training of raters, the intra-rater reliability, and the inter-raters reliability within the study (not to external sources).

This question is about the reliability of the measurement performed in the study, it is not about the validity of the measurement instruments/scales used in the study. *[Note: Two other important threats that weaken the validity of inferences about the statistical relationship between the 'cause' and the 'effect' are low statistical power and the violation of the assumptions of statistical tests. These other threats are not explored within Question 8, these are explored within Question 9.]*

9. Was appropriate statistical analysis used?

Inappropriate statistical analysis may cause errors of statistical inference with regards to the existence and the magnitude of the effect determined by the treatment ('cause'). Low statistical power and the violation of the assumptions of statistical tests are two important threats that weakens the validity of inferences about the statistical relationship between the 'cause' and the 'effect'. Check the following aspects: if the assumptions of statistical tests were respected; if appropriate statistical power analysis was performed; if appropriate effect sizes were used; if appropriate statistical procedures or methods were used given the number and type of dependent and independent variables, the number of study groups, the nature of the relationship between the groups (independent or dependent groups), and the objectives of statistical analysis (association between variables; prediction; survival analysis etc.).

Major Research Project Appendices (Chapter 2)

Appendix 2.1 – Study Protocol

Augmenting psychological treatment for fear of falling using Virtual Reality: A feasibility study in older adults

19.06.2020

Version-1

Actual word-count: 3276

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Abstract

Background

Falls in older adults are expensive to the NHS and reduce patients' quality of life. Fear of falling (FoF) increases the risk of falls and so is an important treatment target. Virtual reality (VR) supported exposure treatments potentially save labour and costs, and can improve FoF; however, few VR treatment protocols have been co-productively designed. This feasibility study will evaluate the acceptability of a custom-designed VR FoF intervention targeting psychological process related to FoF in older adults.

Aims

- Evaluate feasibility, including acceptability and tolerability, of a VR intervention in older adults.
- Determine if patients are willing to participate in this treatment.
- Develop and evaluate FoF measurements within virtual environments.

Methods

Participants with current or past FoF from NHS psychology services will interact with a short VR intervention, involving psychological exposure to commonly feared scenarios. It will be designed in collaboration with computer science colleagues. Outcomes gathered include quantitative anxiety ratings (e.g. Likert scales) within the virtual environment and post-intervention qualitative semi-structured interview feedback.

Applications

Results will form the beginnings of a co-produced intervention. The rich user experience data will aid psychologists and software-developers in designing future automated VR interventions.

Introduction

Background

Approximately one third of older adults (≥ 65 years) fall annually (National Institute for Health and Care Excellence [NICE], 2013). This increases with age, with half of those aged 80 years or older at risk of falling (NICE, 2013). Falls can result in serious injuries, particularly fractures. Amongst older adults, they cost the NHS billions of pounds yearly for outpatients and inpatients (Public Health England [PHE], 2017; NICE, 2018). Annually, emergency hospital admissions cost over £2-billion (NICE, 2018) and social care following fragility fractures costs over £1-billion (PHE, 2017). Despite this, most falls are not seen by healthcare services (Graham & Firth, 1992), with around 80% of non-injurious falls going unreported to healthcare staff (Age Concern, 1997). This is concerning considering past falls can predict future falls (NICE, 2013). Risk factors are intrinsic or environmental (Todd & Skelton, 2004). Unsuitable lighting, walking aids or floor surfaces are extrinsic factors that increase falling risk (Dean & Ross, 1993; Lord et al., 2000). Intrinsic physical and mental health conditions that increase risk include arthritis, depression and stroke (NICE, 2013); multimorbidity further heightens risk (NICE, 2018).

Fear of Falling

Falls drastically reduce quality of life (QoL), with effects including activity avoidance, increased frailty and reduced socialising (PHE, 2017; Arfken et al., 1994). With an ageing population, falls prevention is becoming increasingly important to reduce NHS costs and enhance people's wellbeing (McLean et al., 2015). A fear of falling (FoF) equally impacts QoL, limiting living activities (Suzuki et al., 2002). FoF is defined as people's reduced confidence in their balance abilities (Maki et al., 1991). FoF can develop whether people have fallen previously or not (PHE, 2017), and this fear can increase risk of falling via impaired balance ability (Li et al., 2003).

Young and Williams (2015) describe psychological mechanisms behind this, drawing inferences from Attentional Control Theory (Eysenck et al., 2007). These include increased anxiety which negatively alters attentional movement-related processes. Hence, people become preoccupied with threatening stimuli, or stimuli irrelevant to

movement tasks. They may be consumed with anxious thoughts about slipping and falling, leaving inadequate attentional resources remaining to safely guide movement. This anxiety also reduces ability to retain visuospatial information in their working memory, for example, where obstacles are spatially. Moreover, people stiffen their body to avoid falling, compromising ability during postural tasks with high working memory demands, such as navigating uneven pavements (Young & Williams, 2015).

Interventions: Virtual Reality

Given the role of psychological processes, elements of Cognitive Behavioural Therapy (CBT) have been successfully used to reduce FoF, as well as improve depression and QoL (Parry et al., 2016; Liu et al., 2018). There is a necessity for efficient replicability, improved costs and reduced labour in psychological interventions (Freeman et al., 2018). There is evidence that interventions to reduce falls in older adults can be cost-effective when there is a reduction in medical care costs (McLean et al., 2015). Virtual Reality (VR) is increasingly being used in psychological exposure interventions to address this. VR is defined as an interactive computer simulation in which users' actions are sensed and fed back to one or more senses (e.g. visual or haptic), such that they become immersed in virtual worlds (Mihelj et al., 2014). Its advantages include ecological realism, low physical risk, exposure to situations impossible in reality, and, low monetary and logistical efforts (Fromberger, et al., 2018). A recent meta-analysis found VR exposure therapy to be as effective at improving anxiety disorders as *in-vivo* therapy, as well as having a large effect size (Carl et al., 2019). Some studies have demonstrated specific benefit for anxiety disorders using automated VR-treatment, which is conducive to replicable low-labour therapy (Freeman et al., 2018). VR FoF exposure therapy interventions have had success in reducing anxiety and demonstrated that older adults tolerate the associated head mounted devices (HMDs) (Levy et al., 2016). VR interventions are particularly successful when they include both exposure to challenge FoF beliefs and interaction in the environment to internalise these new beliefs (Levy et al., 2016).

Co-production

Co-production of mental health interventions has been used less than in physical health (Larkin et al., 2015). Co-production is increasingly considered crucial in development of psychological VR interventions. A seminal paper describes three stages for VR healthcare studies to follow to gain the best outcome for end-users (Birckhead et al., 2019). The first stage, “VR1”, focuses on content development to “promote empathy, team collaboration, and continuous user feedback”. VR2 explores “early testing... feasibility, acceptability, tolerability, and initial clinical efficacy.” ‘Acceptability’ is patients’ willingness to use the intervention, ‘Feasibility’ is the extent it can be effectively utilised in current care and ‘Tolerability’ involves evaluating adverse treatment effects, physical or emotional. The final stage, VR3, comprises randomised controlled trials (RCTs). Some CBT-based FoF treatments have co-designed interventions using patient interviews (Parry et al., 2016). However, few VR-based interventions have co-produced interventions, including RCT studies of FoF and other phobias (Carl et al., 2019; Levy et al., 2016). Nonetheless, older adults with FoF tolerate HMDs and experience improved anxiety (Levy et al., 2016).

Consequently, this study combines elements of Birckhead et al.’s (2019) VR1 and VR2 stages, evaluating a FoF VR intervention in terms of feasibility, tolerability and acceptability. VR is not used to treat FoF in NHS settings, making this novel and beginning iterative processes of developing cost and labour saving FoF interventions in a patient centred way.

Aims

- To evaluate the feasibility and acceptability of a VR intervention in older adults, designed to target psychological process related to FoF. Specifically:
 - Determine the tolerability and acceptability of VR as a FoF treatment, gaining qualitative user experience feedback
 - Determine the proportion of FoF patients that are willing to participate in VR interventions
 - Develop and evaluate measurement of FoF outcomes within the virtual environment

Plan of Investigation

Participants

Older adults in contact with NHS services who currently or have historically experienced FoF as diagnosed by Clinical Psychologists.

Inclusion Criteria

Currently or previously treated within NHSGGC older adult services and have/had FoF.

Exclusion Criteria

Never been treated within older adult NHSGGC services or had FoF. Any disorder that undermines capacity to give informed consent.

Recruitment

Current or past patients of NHSGGC Clinical psychology physical rehabilitation services and day hospitals will be approached to participate voluntarily; the primary contact for this being a liaison Clinical psychologist.

Measures

Prior to intervention design, Clinical psychologists and service-users will be consulted via a brain-storming group on acceptability, tolerability and feasibility. Self-rated scales such as the State-Trait Anxiety Inventory (Spielberger, 1983) will gather data within the VR world pre and post-exposure, assessing tolerability. Post-intervention, individual semi-structured interviews will be conducted, gaining qualitative user experience (UX) data to explore acceptability and tolerability. 'Presence' in the environment (feeling within the world) will be measured via a 'sense of presence' questionnaire (Freeman et al., 2003; Slater et al., 1998); higher presence indicates better feasibility as an intervention. Demographics including age, sex and medical/ cognitive conditions will be gathered. A brief cognitive screen, such as Addenbrooke's cognitive examination (ACE-III), could be given beforehand to highlight memory or visuospatial difficulties.

Research Procedures

The study will be largely based on Birckhead et al.'s (2019) VR1 and VR2 research stages, as outlined. A bespoke virtual world will be created in collaboration with the University of Glasgow's Computing School, which includes features targeting FoF-related psychological processes. These will involve psychological exposure and environmental interaction. Virtual environments will incorporate extrinsic risk factors for falling, including varying lighting, weather conditions (snow, rain etc.) or uneven floor surfaces, such as door thresholds (Dean & Ross, 1993; Lord et al., 2000). Specific features of exposure environments will be collectively determined by a group of Clinical psychologists, service-users and researchers familiar with FoF. Participants will use a Likert scale within the world to rate their present-moment anxiety. They will experience this world for a timeframe around 30 minutes or less, wearing wireless Oculus Quest HMDs. Immediately post-intervention, participants will be semi-structurally interviewed on UX, exploring acceptability and tolerability.

As suggested by the main supervisor, the **Appendix** outlines contingency procedures.

Analysis

Users' anxiety ratings and researchers' observations will be reported descriptively, adhering to recommendations on reporting feasibility studies (Arain et al., 2010). Interviews will be audio-recorded, transcribed and analysed thematically (Braun & Clarke, 2006), via qualitative analysis software. As recommended by the UK Medical Research Council (MRC) for intervention evaluation, inferences from quantitative and qualitative data will be combined to strengthen findings. Themes will be reviewed by a second coder to confirm validity (Moore et al., 2015). Other analyses are also possible, including estimating effect sizes, such as rate of anxiety habituation as a function of time exposed in VR.

Sample Size Justification

Research examining older people's perspectives on FoF via interviews have varied in sample size, from under 10 to nearly 100 (McMahon et al., 2011). Generally, those with smaller samples collected "richer" data. The National Institute for Health Research (NIHR, 2017) suggest sample calculations are unnecessary for most qualitative research, but indicate samples must be large enough to reach theme "saturation" and represent target population diversity. A similar co-production study gaining qualitative feedback for a VR psychosis intervention, used 20 participants via convenience sampling (Realpe et al., 2019). Guidelines on "small" thematic analyses suggest under 10 participants can be used (Braun & Clarke, 2013).

Data from an involved NHSGGC older adult psychology service suggest 14 referrals were directly FoF related over the past year (March 2019-20). In addition to the short time-period available and early stages of this research, we will use convenience sampling to recruit around 5 participants. This will be adequate to determine preliminary aspects of feasibility (e.g. resources and timescale), compliance, acceptability and tolerability. Recruiters will track numbers of patients approached vs. those who participate. Within this, we aim to collect quantitative data from all who tolerate the full intervention.

Settings

Physical rehabilitation or day hospital settings.

Equipment

Oculus Quest VR HMDs and associated software, to be determined by University of Glasgow's Computing School colleagues, namely the bespoke virtual world as described earlier. These will be provided by the computing school and borrowed on a day-by-day basis.

Health and Safety

Researcher Safety

Researchers will be briefed on safe use of VR equipment by computing school staff.

Participant Safety

Participants with physical accessibility issues will receive required support (e.g. disabled toilets, ramps). VR-induced side-effects (VRISE) are a potential issue and can include motion-sickness, however they are generally transient and mild (Gregg & Tarrier, 2007; Nichols & Patel, 2002). Participants will be warned of these and can withdraw any time during the research. Risk of actual falls will be low as the intervention will involve participants sitting, which has been effective in past VR FoF studies (Levy et al., 2016).

Ethics

Full written informed consent will be gained. By participating, participants will not be excluded from any current or future FoF 'treatment as usual'.

Finances

VR equipment will be borrowed without charge. We will not financially reimburse participants, but will offer refreshments, requiring a budget of approximately £20.

Printing costs to provide potential participants and clinicians with information will be approximately £20. Recruitment locations are to be determined by the liaison Clinical psychologist, who is the main contact for this. With this current knowledge we do not anticipate any significant researcher travel costs between hospital sites.

Overall Timeline

- March–June 2020
 - Clinical psychology colleagues brain-storm VR environment features, with patient input.
 - Discuss development of VR world with computing school, including identifying an MSc student to complete it.
 - Determine recruitment locations and clinics.
 - Begin systematic review.
- June–December 2020
 - Final MRP proposal and ethics completed.
 - Source clinic rooms and times for collection.
 - MSc student completes programming for VR-world.
 - Begin collecting data.
- January–April 2021
 - Continue and complete data collection.
- April–July 2021
 - Write-up MRP and systematic review.
 - Submission.

Practical Implications

- Beginnings of a co-productive VR FoF intervention creation, using a structured staged process. Such automated interventions could reduce cost and labour (i.e. few therapists needed).
- Gain rich qualitative UX information on VR for FoF.

- Inform later creation of VR FoF virtual worlds.
- First development stage of interventions which could ultimately save the NHS money, via reducing anxiety-related behaviour which increases falls risk.

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Appendix

Table 1: Potential contingency options in light of COVID-19

Plan	Participants	Pre-Intervention	Intervention	Post-Intervention
<p style="text-align: center;">Original</p> <p>(If physical contact <i>is</i> possible with older adults)</p>	<ul style="list-style-type: none"> • Older adults from FoF service 	<ul style="list-style-type: none"> • Possible cognitive screen (ACE-III) • Anxiety questionnaire within VR (STAI – Spielberg, 1983) 	<ul style="list-style-type: none"> • VR Intervention 	<ul style="list-style-type: none"> • Anxiety questionnaire within VR (STAI – Spielberg, 1983) • Sense of ‘presence’ questionnaire (Freeman et al., 2003). • Semi-structured interview including UX questions

<p>Contingency 1</p> <p>(If <i>no</i> physical contact is possible with vulnerable older adults)</p>	<ul style="list-style-type: none"> Older adults from FoF service 		<ul style="list-style-type: none"> Send materials depicting VR Intervention (e.g. screenshots/ video) 	<ul style="list-style-type: none"> Semi-structured phone interview including UX questions
	<p>Adjunct screening sample:</p> <ul style="list-style-type: none"> Younger adults (e.g. students) with or without FoF (or e.g. fear of heights) 	<ul style="list-style-type: none"> Anxiety questionnaire within VR (STAI – Spielberger, 1983) 	<ul style="list-style-type: none"> VR Intervention 	<ul style="list-style-type: none"> Anxiety questionnaire within VR (STAI – Spielberger, 1983) Sense of ‘presence’ questionnaire (Freeman et al., 2003). Semi-structured phone interview including UX questions
<p>Contingency 2</p>	<ul style="list-style-type: none"> Older adults from FoF service 	<ul style="list-style-type: none"> Anxiety questionnaire (STAI – Spielberger, 1983) 	<ul style="list-style-type: none"> Send materials depicting VR Intervention (e.g. screenshots/ video) 	<ul style="list-style-type: none"> Anxiety questionnaire (STAI – Spielberger, 1983)- <i>After viewing specific</i>

(If <i>no</i> physical contact is possible with anyone)				<i>scenario image/ video</i> <ul style="list-style-type: none"> • Semi-structured phone interview including UX questions
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VR = Virtual reality

FoF = Fear of falling

UX = User experience

ACE-III = Addenbrooke's Cognitive Examination 3

STAI = The State-Trait Anxiety Inventory

**Appendix 2.2 – Template for email to NHS GG&C Older People’s
Psychology Service Clinical Psychologists**

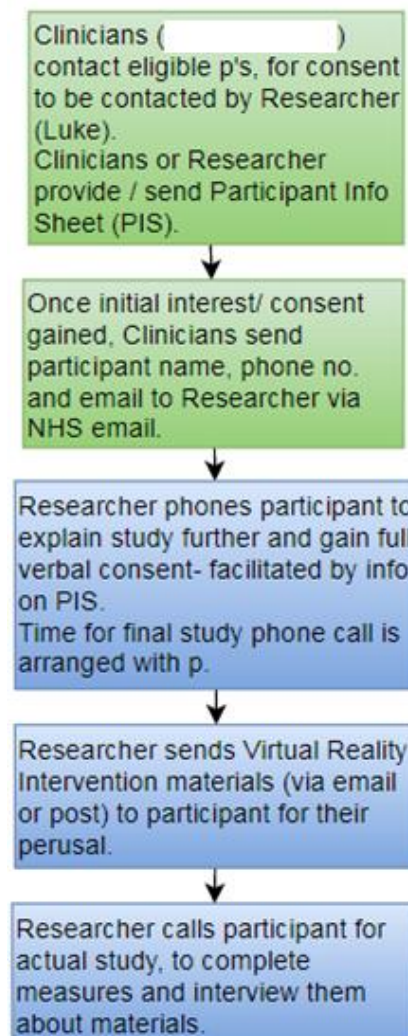
Hi [Recruiting Clinical Psychologists],

[Psychologist 1] and I had a good discussion today around recruitment- Thanks again [Psychologist 2] for outlining the eligible sample numbers.

The main outcome is that we are going to go ahead with recruitment; I'm expected to finish data collection around May. [Recruiting Psychologists] are going to kindly start contacting potential participants for their initial interest, and ask if they consent for the researcher, myself, to contact them via phone. We also have an ethics-approved Participant Information Sheet to send them (attached), or I can send them, before I call - What do you think would be the best way to get this to them?

In this first call I'll explain the study further and gain their verbal consent for the actual study- which will be in a final phone call with myself. Between these two calls I'll post/ email them the VR intervention materials (images & written text) for them to read, which the final structured phone interview will be based on. All we require from you [Recruiting Psychologists] is their name/ phone number (& email if they have one)- which [Psychologist 1] and I agreed can be sent to me via my NHS email whenever you have someone [Primary Researcher’s NHS email].

For ease, here is a preliminary flowchart of the expected process; Green represents your involvement as Clinicians:



[Psychologist 1], you also asked for an example of what you could say to patients to gain initial interest, I was thinking something along the lines of:

- *"We were wondering if you would be interested in taking part in a study on Fear of Falling.*
- *It would involve a trainee Psychologist/ researcher, Luke, calling you to discuss your view on a new treatment for Fear of Falling involving 'Virtual Reality'.*

- *It can be done entirely from home over the phone, and you would be sent information on the treatment, which you will later tell us your thoughts on.*
- *Here is (/we will send) you an information sheet on the study.*
- *You do not have to decide now, however, if you are interested now, do we have your permission to send the researcher your name/ phone number?*
- *This is for Luke to call you to explain more about the study and you can decide whether you want to take part or not."*

Thanks all, I hope this is helpful. I'll be sending some potential times for a next meeting which hopefully we can all attend.

Kind Regards,

Luke

Luke Barracliffe

Trainee Clinical Psychologist

Appendix 2.3 – Summary of Expert and service-user discussion and feedback for VR FoF Treatment

Summary of Expert and service-user discussion and feedback for VR FoF Treatment

Service user:

Primary researcher's telephone discussion with female service user of Older Adult Psychology service in her 60s, working part-time. The recruiting Clinical Psychologists consensually provided her details to the primary researcher.

Aim: To explore her experience and needs around FoF to inform VR treatment design.s

Her experience/ history of FoF

- Has been seeing clinical psychologist (CP) since before Christmas 2019- First time seeing CP, expected only a few sessions, but pleased she's had prolonged input.
- FoF improved a lot but still somewhat present.
- Has experienced multiple falls, some resulting in dental damage and fractures- big source of fears. Has had hip replacement.
- One fall involving a revolving door at her work, which knocked her over.
- Uses a walking stick
- Initially terrified to leave house/ wouldn't unless had to.
- Would park near buildings to reduce walking
- Thoughts of "I'm going to fall", "I can't walk anywhere"
- Had dreams about falling
- Used to be a very independent person- dislikes idea of relying on others.
- Worried if can't take dog for a walk.

- Is able to stay in house during Covid quarantine without facing fears currently- No children at home, so less reason to go out.

What helped improve her FoF

- Has found Psychologist's 'soothing voice' helpful and being told which behaviours increase falling risk (e.g. looking down). Has been gradually going outside/ exposing self to situations- going with her husband helps as he assures her he'll catch her. Has been out alone successfully- felt pleased/ gained confidence.

Fearred environmental factors & related behaviours

- A pebble/ stone on the ground
- Black ice, snow- worries about winter approaching- especially getting dark earlier.
- Will scan ground to see if its even- constantly looks down when scared.
- Busy places- avoids walking near people ("someone's going to bump into me")
- People walking dogs- they'll jump up and unbalance her, or she'll get tangled in the lead
- Using quieter routes or planning routes before
- Inclines/ hills/ uneven pavements- will cross the road to avoid this
- Prefers uphill to downhill
- Unfamiliar routes
- School kids out in streets at lunchtime- avoids this time period
- Imagines others falling (e.g. if sees someone riding fast on a bike)
- Handrails help her- would be worried if weren't any- has asked ahead of going on holidays if accommodation has these and requests ground floor; would still go if didn't get this, but not ideal.
- Prefers lift over stairs.

Perceived participation

- She feels people would be willing to engage- but perhaps not those in early stages of treatment (said she would not have considered it a few months ago, but would now).

Consultant Clinical Psychologist:

Summary of feedback from Older Adult Psychologist over multiple meetings with Computer Science colleagues, the primary research and their supervisor, on VR intervention design.

- ***Initial intervention version from Computer Science Colleague 1:***
 - Greater contrast in colours between ceiling and floor
 - Good range of task situations
 - Incorporate use of a Likert scale
 - Development of a 'tilt alarm'
 - Advice on when this should be triggered- e.g. when walking and looking down
 - Less weathered objects, such as cars
 - Advised on specific outdoor task
 - Discussion of exposure grading
- ***Second intervention version from Computer Science Colleague 2:***
 - Incorporating use of an 'avatar'
 - Very impressed overall- large improvement from previous version in tasks and realism
 - High ecological validity
 - Tasks relevant to older adults, and accurate/realistic visuals
 - Exposure tasks well graded from easy to difficult
 - Potentially more realistic avatar voice/ an actual voice recording- to make it relatable for users

- Minor language/ cultural differences in text- "cell phone" to "mobile phone"

Appendix 2.4 – Mental Health Measures

GAD-7 Anxiety

Over the <u>last 2 weeks</u> , how often have you been bothered by the following problems? (Use "✓" to indicate your answer"	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3

Column totals:

___ + ___ + ___ + ___

= Total Score _____

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult
at all

Somewhat
difficult

Very
difficult

Extremely
difficult

From the Primary Care Evaluation of Mental Disorders Patient Health Questionnaire (PRIME-MD PHQ). The PHQ was developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues. For research information, contact Dr. Spitzer at ris8@columbia.edu. PRIME-MD® is a trademark of Pfizer Inc. Copyright© 1999 Pfizer Inc. All rights reserved. Reproduced with permission

PHQ-9 Depression

Over the last 2 weeks, how often have you been bothered by any of the following problems?

(Use "✓" to indicate your answer"

	Not all	at Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things.....	0	1	2	3
2. Feeling down, depressed, or hopeless.....	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much.....	0	1	2	3
4. Feeling tired or having little energy.....	0	1	2	3
5. Poor appetite or overeating.....	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down.....	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television.....	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual.....	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way.....	0	1	2	3
Column totals	___	+ ___	+ ___	+ ___
	= Total Score _____			

From the Primary Care Evaluation of Mental Disorders Patient Health Questionnaire (PRIME-MD PHQ). The PHQ was developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues. For research information, contact Dr. Spitzer at rls8@columbia.edu. PRIME-MD® is a trademark of Pfizer Inc. Copyright© 1999 Pfizer Inc. All rights reserved. Reproduced with permission

Scoring notes.

- *PHQ-9 Depression Severity*

Scores represent: **0-5 = mild** **6-10 = moderate** **11-15 = moderately severe**
16-20 = severe depression

- *GAD-7 Anxiety Severity.*

This is calculated by assigning scores of 0, 1, 2, and 3, to the response categories of "not at all," "several days," "more than half the days," and "nearly every day," respectively. GAD-7 total score for the seven items ranges from 0 to 21.

Scores represent: **0-5 mild** **6-10 moderate** **11-15 moderately severe anxiety**
15-21 severe anxiety.

FES-I – Falling Concern

Now we would like to ask some questions about how concerned you are about the possibility of falling. For each of the following activities, please circle the opinion closest to your own to show how concerned you are that you might fall if you did this activity. Please reply thinking about how you usually do the activity. If you currently don't do the activity (e.g. if someone does your shopping for you), please answer to show whether you think you would be concerned about falling IF you did the activity.

		<i>Not at all concerned</i>	<i>Somewhat concerned</i>	<i>Fairly concerned</i>	<i>Very concerned</i>
		<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>
1	Cleaning the house (e.g. sweep, vacuum or dust)	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>
2	Getting dressed or undressed	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>
3	Preparing simple meals	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>
4	Taking a bath or shower	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>
5	Going to the shop	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>
6	Getting in or out of a chair	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>
7	Going up or down stairs	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>
8	Walking around in the neighbourhood	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>

9	Reaching for something above your head or on the ground	1	2	3	4
10	Going to answer the telephone before it stops ringing	1	2	3	4
11	Walking on a slippery surface (e.g. wet or icy)	1	2	3	4
12	Visiting a friend or relative	1	2	3	4
13	Walking in a place with crowds	1	2	3	4
14	Walking on an uneven surface (e.g. rocky ground, poorly maintained pavement)	1	2	3	4
15	Walking up or down a slope	1	2	3	4
16	Going out to a social event (e.g. religious service, family gathering or club meeting)	1	2	3	4

Scoring: 16-19= Low falling concern, 20-27= Moderate, 28-64= High.

Tinetti, M., Richman, D., & Powell, L. (1990). Falls efficacy as a measure of fear of falling. *Journal of gerontology*, 45(6), 239.

Appendix 2.5 – Intervention materials



Using Virtual Reality to treat Fear of Falling

Participant Handout

Thank you for agreeing to participate in our study. As discussed in our last phone call, you have been sent these materials to review before we call you to ask you your thoughts on them. Please take your time to read through this and look at the images. You do not have to read it all at once and you can take breaks, but try and look at all the information.

Introduction

We are developing a new Virtual Reality (VR) treatment to help people with their fear of falling. It will involve practising tasks people may do in the real world in order to reduce their anxiety and reduce the risk of falls. Before we physically test this on anyone, we would like people like yourself to read about and look at what we have developed and provide us with valuable feedback. This document outlines what would happen during the treatment.

Equipment

Virtual reality, or 'VR', is a computer-generated environment which is interacted with in a realistic and immersive way. It often uses goggles or a headset through which users can experience the virtual environment. Users can look and walk around in the virtual environment as they would in the real world. In the treatment we are developing, users would wear this headset and also hold a controller with buttons in each hand, to interact with the environment. These are widely and successfully used for other purposes, such as video games. Some people might experience side-effects like motion-

sickness; however, these are usually mild and disappear quickly. The headset can easily be taken off at any time and there would be a clinician present to support the user. Examples of the equipment are pictured below:



The Treatment

When the user puts on the equipment and the treatment begins, they will be greeted by a virtual person, or 'avatar', who will act as their clinician. The avatar is designed to be a friendly and helpful guide who supports the user in treatment by talking to them. Written instructions are also provided in the virtual environment. The controllers the user holds enables them to interact with things in the virtual environment by pointing and clicking, to select or manipulate objects. The user will also see a virtual pair of hands wherever they point the controllers they are holding. An example is provided below:



To help the user interact with items, such as buttons, there is a pink line or 'laser' which aims wherever they point.

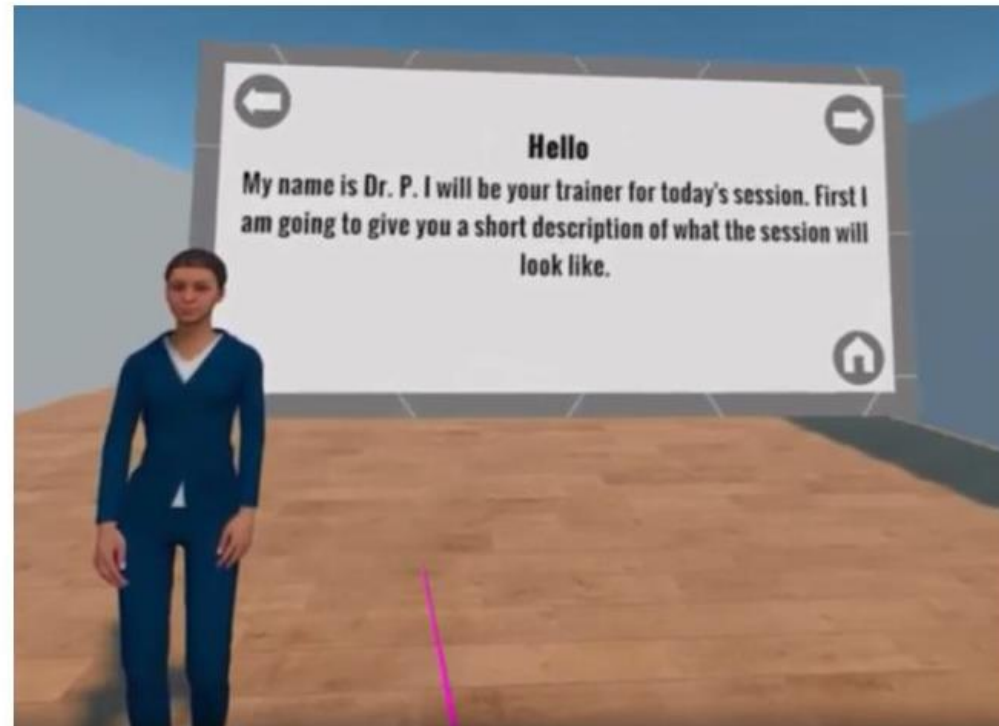
This image shows the user pointing at an arrow button for example:



The image below shows the first view the user would see, including the avatar and a screen providing instructions. The avatar would also be reading these instructions:



Here is another example of the menu screen. The user can select the arrows to move through the instructions:



Once the avatar has introduced the treatment, the user can choose tasks to complete which are similar to those they might do in the real world, such as opening a cupboard or answering a phone. These tasks are graded from easy to hard. The idea is to gradually work up to more challenging tasks. As the user does this and gets used to each task, their anxiety and fear of falling is expected to gradually reduce. Tasks can be repeated as many times as the user would like.

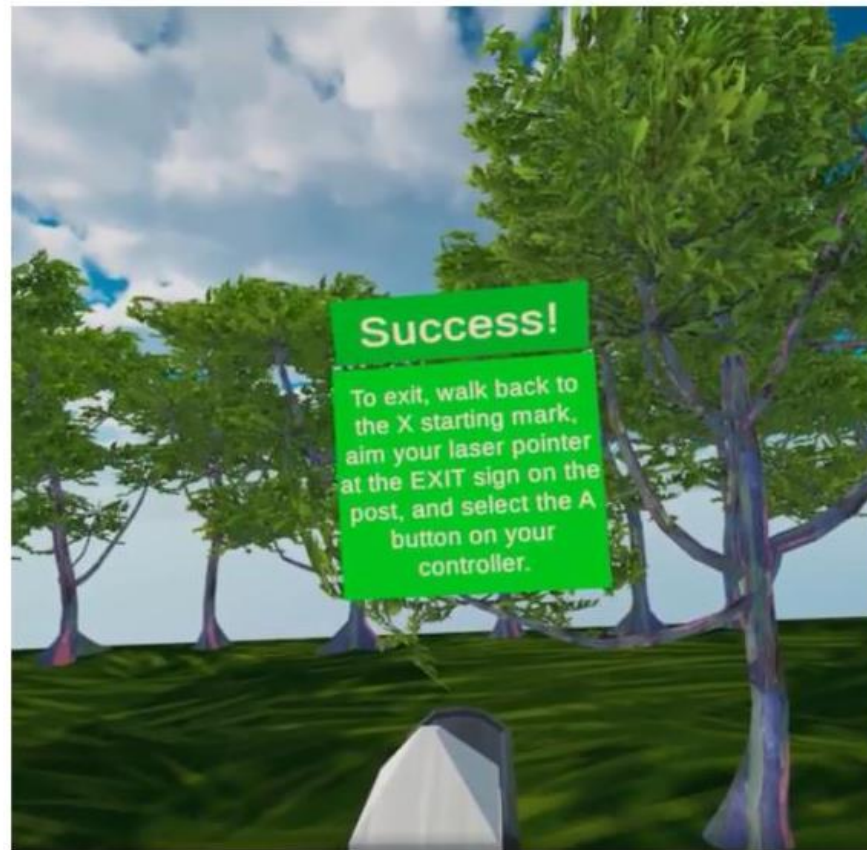
This is what the task selection menu would look like. In this example, the menu outlines the tasks and the location where the task is to be completed, such as picking up a magazine in the living room. This menu depicts the 'easy' difficulty tasks for the user to choose from:



Here is an example of a task graded as 'easy' difficulty. The environment is a front garden, and the task is to walk to the post box/ mailbox, the location of which is highlighted with a green light. The avatar will also verbally remind the user of the task:



Once a task has been successfully completed, a message like this appears, with instructions on how to return to the task menu. This requires walking back to the start point and selecting an "Exit" sign, like the one shown below left:



This is another example of a task graded as 'easy', The environment is a kitchen and the task is to open the top cupboard. The cupboard location is highlighted with a green light:



This shows the user's virtual hand reaching to open the cupboard to complete the task:



This is an example of a task graded as 'medium' difficulty. Again, the task is to walk to the post box. However, this time the light is dimmer, and the post box is lower; meaning that the user must bend to around waist height to reach it. This makes the task more challenging:



There are also some obstacles blocking the path which the user must navigate. If the user accidentally touches or walks through an object, the controllers will vibrate to alert them to this error:



This is another example of a task graded as medium difficulty. The environment is a living room and the task is to reach the TV remote to mute the TV, which requires navigating around furniture. The lighting is slightly dim, and the remote control is at waist height. The TV is also audible:



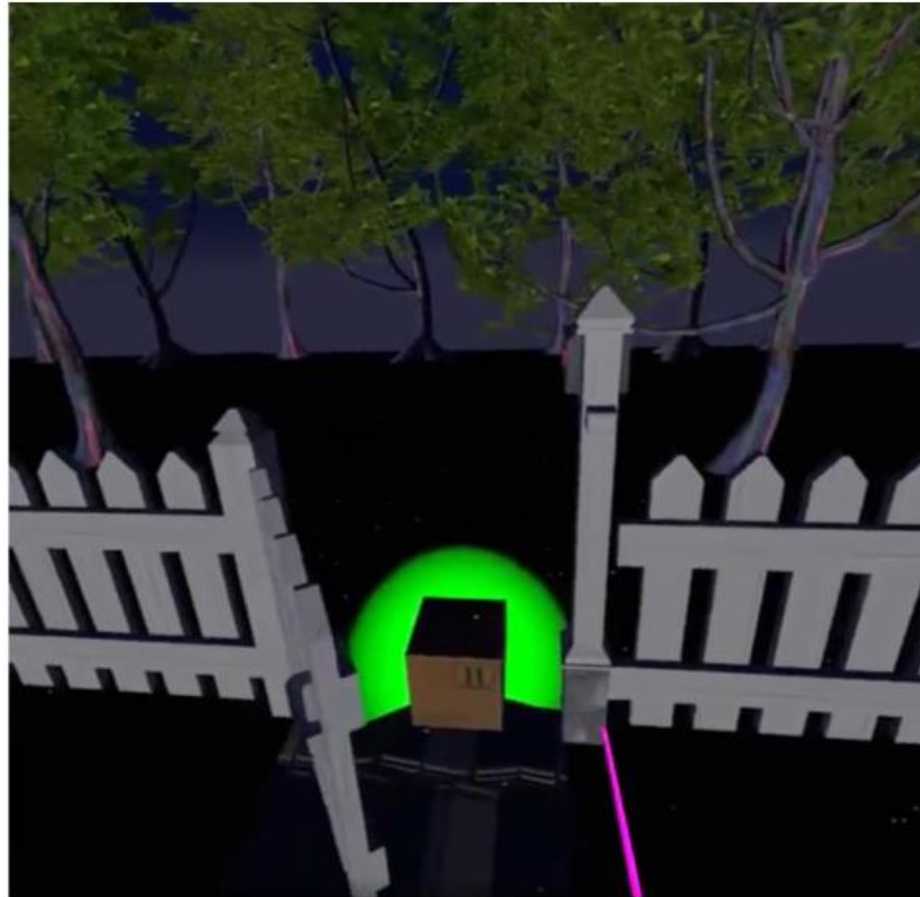
This shows the TV remote on the table, highlighted in green:



This is an example of a task graded as 'hard' difficulty. The environment is the garden and the task is to pick up a package on the ground. Added challenges include the reduced lighting conditions and stormy weather, including hail and thunder sounds. There are obstacles to navigate on the path and retrieving the package requires bending down:



This is the package on the ground:



This is another example of a harder task. The environment is a bedroom and the task is to answer a ringing phone, highlighted in green. Again, the lighting is dim and there are obstacles to navigate around, such as the bed and a chair. The phone is on a low surface that requires bending:



This shows the user reaching for the mobile phone, highlighted by a green light:



In order to track the effect of completing these tasks on the users' anxiety levels, everyone will be asked to rate their anxiety before and after completing each task. The range of scores include 'very relaxed', 'relaxed', 'neutral', 'anxious' and 'very anxious'. These ratings will be tracked so that users can see whether their fears reduce after a task. Here is an example of this scale:



This shows the user selecting an option from this scale:



Another feature of the treatment is a 'tilt alarm' which makes a sound whenever a user looks down at their feet whilst both tilting forward and walking. This alarm is included in the program because people tend to look down at their feet instead of their surroundings when they are fearful of falling. This alert aims to help users notice when they do this and it is expected that this feedback will reduce this unhelpful behaviour. Users will be told how many times they set off the tilt alarm after completing each task. An example of this is shown below, along with other information, such as time taken to complete the task:



What happens next?

Thank you for taking the time to carefully read and think about this document. As explained during the recruitment and consent call, the next step involves having an interview with the researcher to discuss your views on this new Virtual Reality treatment for fear of falling. You do not need to prepare anything for this, only have this document with you for the call. Your feedback is most important and highly valued. We look forward to speaking with you.

Luke Barracliffe, Trainee Clinical Psychologist

Luke.Barracliffe@ggc.scot.nhs.uk; l.barracliffe.1@research.gla.ac.uk

&

Hamish McLeod, Professor of Clinical Psychology, University of Glasgow

Hamish.McLeod@glasgow.ac.uk; 0141 211 3922

Appendix 2.6 –Semi-structured interview process & schedule

Virtual Reality Intervention for Fear of Falling:

Semi-structured interview schedule

Phone call 1 to participant:

Approx. 10-20min

- Researcher answers any queries on study and consent procedure.
- Researcher gains verbal consent using consent document as reference, which participant received previously from NHS clinician.
- Mutually arrange date and time to call for main study, approximately one week or more from expected arrival time of VR materials.

Researcher sends participant VR example materials

Phone call 2 to participant:

Approximately one week after materials are received, as agreed with participant in first call.

Approx. 30-75min total

- Demographic questions
- Complete 3 questionnaires (15-45min):
 - o PHQ-9, GAD-7, FES-I
- Semi-structured interview (15-30min):

Main topic	Probing questions
General impressions	<ul style="list-style-type: none">- What are your overall impressions of the intervention?- <i>Does it appear to be a positive experience?</i>- Does it look realistic?- What do you think of the 'tilt alarm' feature?- Are the tasks realistic/ relevant to you?
Acceptability	<ul style="list-style-type: none">- Would you be willing to try this intervention?- <i>What would encourage you to try it?</i>- <i>What makes you feel unsure about trying it?</i>
Feasibility	<ul style="list-style-type: none">- Does it meet your needs for helping fear of falling (EoE)?- Can you see this being part of regular treatment for EoE (treatment as usual)?
Tolerability	<ul style="list-style-type: none">- What do you think of the Virtual reality induced symptoms and effects (VRISE)?- Do you foresee any other issues with trying/ completing the intervention?

- Ask participant if they would like summary of study findings

These questions are based on recommendations for exploring user experience of VR via semi-structured interviews and on past research using these methods (Birckhead et al., 2019; Jung et al., 2017).

References:

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West Midlands - South Birmingham Research Ethics Committee

Attendance at PRS Sub-Committee of the REC meeting on 16 February 2021

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Peter Guest	Retired Consultant Radiologist	Yes	
Dr Elizabeth Hensel	Consultant Clinical Psychologist	Yes	
Dr Kathryn Kinmond	Psychologist and University Lecturer	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Ms Amy Peters	

Appendix 2.9 – Thematic Analysis Log of discussions with second researcher

Log of Thematic Analysis discussions with second researcher:

Each meeting occurred in private with the two researchers present only. The primary researcher's proposed themes were presented and openly discussed to invigorate thinking and increase immersion into the data. They were not 'approved' or 'coded' by the second researcher, as per Braun & Clarke's (2006, 2019) approach.

Meeting 1:

- Discussed deductive-inductive approach.
 - o Agree this as best given a priori question themes, based around study aims.
- Discussed demographics and nature/ context of data from this
 - o I.e., lower SIMD, all female, no male perspectives of VR intervention etc.
- Agree on most themes as generally reflective of data.
- Discussion led to division of theme '**Certainty and safeness**', to create '**Engagement and trust**'.
 - o Initially combined but separated due to tentativeness of some statements in the latter theme, not fitting the original.

Meeting 2:

- Discussed primary researcher's reflections on data.
 - o Overall participants' positive impressions of the intervention, with some points for improvement.
 - o Reflected on fact that some suggested improvements are more

possible than others.

- E.g., Creation of additional tasks (possible) vs. Removal VR sideeffects (not easily possible).
- Discussed **'Relevance to real life'** and **'Task choice & difficulty'** themes.
 - Led to combining these to **'Task relevance, choice & difficulty'**, as definitions were too similar.
- Discussed **'Additional VR features'** and **'Task relevance, choice & difficulty'** themes.
 - Former sub-theme also merged with the latter, as not enough data points for **'Additional VR features'** alone, and too similar in content.

Appendix 2.10 - Manuscript Submission Guidelines: “Journal of Computers in Human Behavior”. (<https://www.elsevier.com/journals/computers-in-human-behavior/0747-5632/guide-for-authors>)

This write-up is transferable to the guidelines of the target journal. Some minor elements differ, for instance, their recommended ‘Introduction’ and ‘Theory’ sections are conflated, allowing readers to smoothly follow the project as a thesis.

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- Ensure all figure and table citations in the text match the files provided
- Indicate clearly if color should be used for any figures in print

Graphical Abstracts / Highlights files (where applicable)

Supplemental files (where applicable)

Further considerations

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Electronic artwork

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