Rigour Meets (Virtual) Reality: Balancing Robust Methodology and Real-World Implementation in a VR-Therapy Protocol for At-Home Dementia Care

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Abstract

Caregivers of people living with dementia (PLwD) experience substantial psychosocial burden, compounded by limited access to formal respite due to financial, geographic, and systemic barriers. Immersive virtual reality (VR) shows promise for alleviating behavioural and psychological symptoms of dementia while supporting caregiver respite. However, current VR studies are often constrained by restrictive eligibility criteria, high participant burden, and selective outcome measures that fail to capture routine use in practice. This paper offers methodological commentary on the VR&R study protocol, a 6-week randomized crossover trial comparing Solo-VR and Social-VR delivery in 50 caregiver–PLwD dyads. The primary outcome is respite, assessed as both objective time away from caregiving and subjective quality, along with secondary outcomes related to caregiver and PLwD well-being. Feasibility, accessibility, and implementation considerations were integrated alongside rigorous methodological features including randomized crossover allocation, mixed-methods evaluation, standardized outcome measures, and objective usage data, informed by advisors, community partners, and people with lived caregiving experience. Key adaptations included eligibility criteria based on functional capacity and assent, expanded caregiver definitions, flexible home-based delivery, and low-burden measures. By combining outcome evaluation with delivery models that reflect everyday care conditions, this study examines not only whether VR can support respite, but also how delivery models and intervention design shape its impact, uptake, and applicability in dementia care.

1. Introduction

Dementia is a leading cause of disability globally, with major impacts on individuals and caregivers. Behavioural and psychological symptoms of dementia (BPSD), including agitation, apathy, and depression, are major contributors to caregiver burden and reduced quality of life (Gitlin & Hodgson, 2015). Although respite services exist, access remains limited by financial, geographic, and systemic barriers. Immersive virtual reality (VR) has emerged as a promising tool for therapeutic engagement among people living with dementia (PLwD), offering safe, customizable experiences deliverable in the home. Emerging evidence suggests VR is feasible, acceptable, and may support mood and engagement in PLwD (Appel et al., 2023), with prior VRx@Home work informing this protocol. However, existing studies are constrained by small samples, short durations, and lack of comparator designs, often relying on global burden or quality-of-life scales

(e.g., HRQoL-14) that do not capture real-world use. More critically, VR engagement has not yet been systematically examined as a mechanism for caregiver respite – a priority identified by community partners, lived experience collaborators, and prior VRx@Home participants (Appel et al., 2023). Dementia trials also frequently exclude individuals with advanced impairment due to rigid eligibility criteria, limiting generalizability and reinforcing inequities (Franzen et al., 2021). Recruitment and retention are further constrained by participant burden, particularly for highly strained dyads (Appel et al., 2023; Saryazdi et al., 2024). There is increasing emphasis in trial methodology on designing studies that reflect real-world care contexts (Loudon et al., 2015). To our knowledge, this is among the first randomized trials to evaluate immersive VR as a mechanism for caregiver respite in dementia care.

In this protocol, we describe the VR&R study, a pragmatic randomized crossover trial evaluating whether VR engagement by PLwD can provide meaningful caregiver respite in home settings. Drawing on broader conceptualizations of caregiver relief and support (Gitlin & Hodgson, 2015), respite was operationalized as both objective time away from caregiving and subjective quality. The study compares Solo-VR (caregiver-supported) and Social-VR (RA-facilitated) models to examine differences in use and respite. The primary objective is to assess respite quantity (time in VR vs time away from caregiving) and quality (perceived relief, reduced vigilance, activities completed). The comparison tests a mechanistic hypothesis that caregiver respite depends not only on PLwD engagement, but on the caregiver's capacity to disengage. Social-VR is designed to reduce caregiver vigilance through external facilitation, while Solo-VR relies on caregiver-mediated supervision, allowing us to examine the role of caregiver substitution in generating respite. Secondary objectives assess caregiver and PLwD well-being across functional, neuropsychiatric, burden, and psychological domains, alongside feasibility of implementation. The study also examines how variability in use and delivery shapes outcomes. In this paper, rigour refers to both internal validity and real-world applicability, supported through a randomized crossover design, mixed-methods evaluation, and objective usage data. Together, these elements enable both causal inference and ecological validity in a home-based context. Supplemental Materials *(SM)* including study procedures, training resources, recruitment materials, and a full list of measures and data collection tools can be accessed here: (https://osf.io/d2c5e/files/osfstorage).

2. Methods

2.1. Study Design

The VR&R study is a 6-week open-label randomized crossover trial involving 50 caregiver–PLwD dyads (n=100). Participants are randomized to Solo-first or Social-first conditions, each delivered over two weeks followed by a two-week follow-up *(SM – Study Timeline)*. This allows observation of each dyad under both delivery models while maintaining flexibility. Data collection began in February 2025 and will continue through January 2027.

2.2. Eligibility and Recruitment

Participants are recruited through community organizations, clinical services, and outreach channels *(SM – Recruitment Flyer; Information for Recruitment Partners)*. Eligibility is based on the PLwD's ability to signal discomfort or disengage, including through non-verbal cues, rather than strict cognitive thresholds, aligning with person-centered care principles (Gitlin & Hodgson, 2015). No language restrictions are applied for PLwD, and research assistants (RA) are matched by language when possible; alternative communication strategies are used when needed. Caregiv-

ers include both informal and formal providers, reflecting real-world care contexts *(SM – Eligibility Screening; Consent Forms)*. This inclusive definition was adopted to reflect heterogeneity in caregiving arrangements across home and community settings, in addition to stakeholder input and interest.

2.3. Intervention Design and Delivery

The intervention uses a Meta Quest 2 head-mounted display paired with a caregiver-controlled tablet interface and caregiVR software (caregiVR Inc., 2026), which provides access to a large library of curated 360° content (e.g., nature, travel, music), developed in alignment with therapeutic recreation principles. Content selection and design were optimized for home-based use through iterative user feedback and implementation, with a focus on viewer experience, engagement, reminiscence, and emotional safety (Appel et al., 2023). The platform enables a shared experience through casting to the tablet, supports a range of cognitive and physical abilities through a simplified caregiver interface, and minimizes interaction demands by removing the need for handheld controllers *(Figure 1, SM – Video Links)*. The intervention protocol allows dyads to determine timing, duration, supervision, and engagement mode *(SM – Baseline Session)*. Participants are encouraged to engage in 30-minute sessions 2–3 times weekly, though use is flexible. PLwD retain choice over content, duration, and feedback. In Solo-VR, caregivers initiate and supervise sessions, while in Social-VR, a trained RA acts as a friendly visitor to facilitate sessions *(SM – Social Visits)*. The two delivery models were designed to reflect real-world variability in dementia care, where support may be either caregiver-mediated or externally facilitated depending on available resources and caregiver capacity. Initial onboarding is conducted in-home by the study coordinator. PLwD are introduced gradually with ongoing assent via verbal and non-verbal cues. Caregivers receive training on setup, supervision, and safety, and a one-page tip sheet with instructions on session flow and technology set-up. The research coordinator proactively checks in with the caregiver throughout the study and caregivers are encouraged to reach out for technical support *(SM – Tip Sheet)*.

2.4. Low Burden and Context-Sensitive Measurement

Caregivers complete a paper-based respite log after each session and a targeted set of brief questionnaires (Clinical Frailty Scale, PAQ-8, NPI-Q, ZBI-6, WHO-5, CD-RISC, SUS). The primary outcome is respite, defined as objective time away and subjective quality. PLwD complete no formal questionnaires; their experience is captured via brief mood ratings, experience scores, caregiver proxy, and RA observations. Passive headset data quantify use. Qualitative interviews *(SM – Interview)* and RA notes capture contextual influences including engagement, safety, and relational dynamics *(SM – Outcome Measures)*.

Figure 1: Social-VR session setup. A trained RA facilitates a Social-VR session with a PLwD using the Meta Quest 2 and caregiVR platform on a paired tablet for real-time casting and content selection.

3. Discussion

Despite rapid growth in VR dementia research, translation into practice remains limited. VR can support momentary mood and engagement, but evidence for sustained clinical effects is limited by small samples, short durations, and variable designs (Wang et al., 2025). Standardized scales may have limited sensitivity to episodic, context-dependent changes in caregiver relief. VR is also highly sensitive to how it is delivered. Unfamiliarity, caregiver mediation, and safety considerations are key limitations that open a gap between efficacy under controlled conditions and effectiveness in real-world home care settings.

The VR&R protocol addresses these challenges through flexible design, expanded eligibility, and implementation-informed adjustments. These reflect the realities of home-based dementia care, where variation in use is expected (Franzen et al., 2021). Data collection and intervention design were built on prior VRx@Home pilot refinements to enhance ecological validity in home settings. A key mid-study refinement was to define eligibility based on the ability of the PLwD to communicate discomfort or the desire to stop the intervention for safety reasons, rather than using a fixed cognitive cut score, thereby broadening inclusion to individuals able to safely participate and potentially benefit. A further contribution is operationalizing respite as both time and experience, capturing when caregivers step away and how meaningful that relief is. The comparison of Solo-VR and Social-VR and participants' choice in actual usage addresses feasibility and respite mechanisms, treating the intervention delivery model itself as a variable that shapes how respite is realized. Understanding whether respite emerges depends not only on intervention efficacy, but on the degree to which caregivers can safely disengage during use, which is itself shaped by delivery models and contextual constraints. Solo-VR offers flexibility but may be limited by vigilance and technical demands. Social-VR enables greater disengagement through facilitation and support. Rigour is supported through a randomized crossover design, mixed-methods evaluation, standardized outcomes, objective usage data, and pragmatic implementation. Key determinants of success include usability in the home environment, caregiver capacity to support or disengage from sessions, and participant comfort during gradual onboarding.

Although the trial design prioritizes pragmatic delivery and minimizes participant burden, this approach entails trade-offs in control and standardization, particularly in a home-based crossover context where variability in use is expected. The short intervention periods may be insufficient to detect sustained changes in caregiver burden or well-being, and caregiver-focused outcomes may not fully capture broader or longer-term impacts. PLwD outcomes are assessed primarily through proxy reports and brief observational measures, limiting insight into direct subjective experience and longer-term effects. More generally, established standardized scales may have limited sensitivity to episodic, context-dependent aspects of caregiver relief and respite, consistent with limitations in capturing real-world care outcomes. While widely used measures were retained for comparability across studies, interpretation must consider the constraints of measurement sensitivity and timeframe in dementia care research.

4. Conclusion

This protocol demonstrates how clinical trial methodology can be integrated with design choices that reflect the realities of dementia care, including structural, ethical, and practical barriers such as language, cognitive inclusion, and caregiver burden (Franzen et al., 2021). By prioritizing accessibility, minimizing burden, and embedding measurement within use, the protocol supports evaluation approaches suited to complex, home-based care. Home-based VR also introduces practical considerations, including setup and maintenance, and long-term adoption will depend on embedding these processes into care systems (Appel et al., 2023). More broadly, the study contributes a model for designing interventions that are both clinically promising and implementable, and for examining how delivery context shapes outcomes (Loudon et al., 2015; Wang et al., 2025). Together, these principles extend beyond VR and dementia care, offering guidance for trials seeking to generate meaningful and actionable evidence in practice.

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Authors SLF, DT, and LA are shareholders in the caregiVR Inc. company. During the preparation of this manuscript, the authors used ChatGPT (OpenAI) for language and structural editing, including sentence shortening, clarity improvement, and identification of repeated information. The authors reviewed and edited the output and take full responsibility for the content of this publication.

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