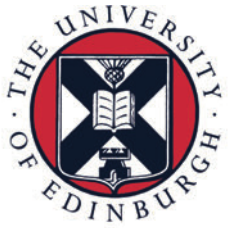

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Technology-based non-pharmacological interventions for stress and distress in dementia care: a systematic review

and

A mixed-method multiple-baseline single-case study exploring the impact of the Tovertafel (Magic Table) on factors impacting staff burnout in an acute dementia care hospital ward.

Fiona Beaton

Doctorate in Clinical Psychology

June 2020

Declaration of own work

Name: Fiona Beaton
Title of Work: Technology-based non-pharmacological interventions for stress and distress in dementia care: a systematic review and A mixed-method multiple-baseline single-case study exploring the impact of the Tovertafel (Magic Table) on factors impacting staff burnout in an acute dementia care hospital ward.

Exploring the perceptions and experiences of mothers and staff using Interpretative Phenomenological Analysis and Thematic Synthesis.
I confirm that this work is my own except where indicated, and that I have:

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Thesis Portfolio Abstract

Technology-based non-pharmacological interventions are a fast-growing area of dementia care and are being applied in a variety of care settings. Due to the readily available nature of many technology-based interventions which often have high face validity and are perceived to have very minimal side effects, research can lag behind clinical applications. Current research suggests that these interventions may be beneficial people to with dementia, but the extent of their effectiveness in specific aspects of dementia care and the impact on the wider care system is still being determined.

A systematic review of the literature was conducted to review the effectiveness of technology-based non-pharmacological interventions on stress and distress in dementia care settings. The term 'stress and distress' encompasses behaviour, affect, perception or thought disturbance symptoms in dementia, such as depression, anxiety, agitation, poor sleep and high levels of distress. While there is evidence that technology-based non-pharmacological interventions can be effective in reducing for stress and distress for people with dementia, the findings of the studies included in the review are mixed, meaning that there is not yet a clear indication of which, if any interventions are most effective. These results are discussed in relation to findings from other studies, with recommendations for future research and clinical applications.

Current research on technology-based non-pharmacological interventions in dementia care often fails to consider staff as a significant factor in the application of interventions. A mixed-method multiple-baseline single-case study methodology was used to assess the impact of the Tovertafel, a technology-based non-pharmacological intervention, on factors related to staff burnout in an acute dementia care ward. The Tovertafel (meaning Magic Table in Dutch) is a digital projection device which provides an interactive and playful recreation activity for people with dementia. The results suggested that the majority of participants demonstrated improvement in factors related to burnout, and a meta-analysis suggested small to medium effect sizes across participants. The thematic analysis of a qualitative staff experience questionnaire established three themes: patient's positive engagement and response to the Tovertafel; benefits to staff from using the Tovertafel; and opportunities to enhance care with no changes to the normal workload. These results suggest that the Tovertafel may have the potential to improve staff outcomes in relation to burnout factors.

Potential directions for future research are discussed.

Thesis Portfolio Lay Summary

Technology-based interventions (such as tablets, media devices and robots) are a fast-growing area of dementia care and are being used in a variety of care settings. These interventions offer an alternative to medication-based approaches when providing care for people with dementia. Due to technology-based interventions being easy to access and often appearing, at face value, likely to benefit people with dementia, they can often be used in care settings before being thoroughly researched. Current research suggests that these interventions may be beneficial to people with dementia. However, more research is needed before we can fully understand how effective they are across different aspects of dementia. The effect they might have on the broader network of people and services involved in caring for a person with dementia also needs to be considered.

A systematic review of the current literature was conducted to examine the effectiveness of technology-based interventions on stress and distress in dementia care. The term ‘stress and distress’ relates to symptoms such as depression, anxiety, agitation, poor sleep and high levels of distress which are experienced by many people with dementia. The findings of the studies in the review generally suggest that technology-based interventions can be effective in reducing stress and distress for people with dementia. However, this was not clear in all studies, meaning it is difficult to know which type of intervention, if any, is most effective. These results are discussed in relation to findings from other studies, with recommendations for future research and the 'real-world' application of these interventions.

Current research on technology-based interventions in dementia care often fails to consider the impact that staff can have on how the intervention is put in to practice. One example of a technology-based intervention is the Tovertafel (meaning “Magic Table” in Dutch). The Tovertafel is a digital projection device which provides an interactive and playful recreation activity for people with dementia. A study using repeated questionnaires to gather information about staff experiences at an individual level over time was developed to understand the impact of the Tovertafel on staff in a dementia care ward. The questionnaires gathered information on aspects of burnout, a psychological experience related to emotional stress and strain at work. The results of the study suggested that the majority of staff members taking part in the study showed improvement in their individually measured aspects of burnout. When assessing the change across all the staff members taking part in the study, small to medium-sized improvements were found. An analysis of responses to a staff experience questionnaire found three main themes: patient’s positive engagement and response to the Tovertafel; benefits to staff from using the Tovertafel; and opportunities to enhance care with no changes to normal workload. These results suggest that the Tovertafel may have the potential to reduce staff burnout. Potential directions for future research are also discussed.

Chapter 1 – Systematic Literature Review

Technology-based non-pharmacological interventions for stress and distress in dementia care: a systematic review

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Abstract

Objective: To review the effectiveness of technology-based non-pharmacological interventions on stress and distress in dementia care settings.

Design: A systematic literature review was conducted, with 11 databases searched for relevant studies from 2000-2020. Quality appraisal and RE-AIM (Reach, Efficacy, Adoption, Implementation and Maintenance) analyses were conducted.

Setting: Home, community and residential care settings.

Participants: People with a diagnosis (confirmed or probable) of dementia of any severity, accessing a relevant intervention.

Interventions: Technology-based non-pharmacological interventions, accessed by the person with dementia, excluding interventions solely used as alarm systems or delivery methods for other therapies.

Results: From 1636 papers, 20 studies met criteria for inclusion. Two studies utilised multimedia technology, five used tablet, touchscreen or computer devices and 13 used robotic devices. Improvements in overall stress and distress and agitation were reported in each type of intervention; however, results across studies were mixed and at times, conflicting. The quality of studies was low to moderate and clinical implementation was often not well considered.

Conclusion: While there is evidence that technology-based non-pharmacological interventions can prove effective in reducing stress and distress, the current literature is unclear as to which, if any interventions are most effective and what the effective components are. Future research should seek to compare and contrast technological interventions on efficacy while considering factors such as staff influence and clinical implementation. Those adopting these interventions in clinical settings should seek to implement them with a flexible, person-centred approach.

Keywords: Dementia; technology; intervention; non-pharmacological; stress and distress; BPSD

Introduction

Non-cognitive symptoms of dementia, which fall in the clusters of behaviour, affect, perception or thought disturbance are thought to affect 75-97% of people living with dementia (PLWD) across community and institutional care settings (Cerejeira *et al.* 2012; Steinberg *et al.* 2007; White *et al.* 2017). These symptoms can include depression, anxiety, agitation, poor sleep and high levels of distress. James & Jackman (2017) noted many terms to collectively describe these symptoms, which include 'challenging behaviour', 'behaviours that challenge' 'neuropsychiatric symptoms of dementia' and 'Behavioural and Psychological Symptoms of Dementia' (BPSD). Significant debate surrounds the use of these terms, particularly concerning the problem of implied causation and increasing stigmatisation which makes them less than satisfactory (Cunningham *et al.* 2019; James & Jackman 2017). Therefore, the alternative term ‘stress and distress’ has been used increasingly in Scotland (Alzheimer Scotland, 2018; Edgar, 2017; NHS Education for Scotland, 2012; The Scottish Government, 2017) and was the term most frequently ranked in the top five by professionals and carers in a recent study examining preferred terms for these symptoms (Wolverson *et al.* 2019). Stress and distress draws from the understanding that behaviours are indicative of a PLWD’s unmet needs (Cohen-Mansfield 2001). The term stress and distress also allows for a shift from a medical model of the difficulties experience by PLWD and those caring for them, to more biopsychosocial models (Spector & Orrell 2010). These models recognise that factors such as environment, attitudes of others, and care approaches have a significant impact on the individual and must be considered when intervening in stress and distress. The term ‘stress and distress’ will be used throughout this review to encompass all the terms described above.

The impact of these symptoms on caregiver burden, risks to the longevity of placement, quality of care and financial implications for the healthcare system, in addition to the significant negative impact on the wellbeing and quality of life of PLWD, are considerable (Barton *et al.* 2016; Kales *et al.* 2015). Policies, such as the 10-Point National Dementia Care Actions in Hospitals Plan (Scotland) (Dementia Standards in Hospitals Implementation and Monitoring Group, 2015) are therefore recognising safe and efficient approaches to stress and distress as a priority.

Treatment for stress and distress has moved away from the use of antipsychotic medications as a first-line treatment, given that evidence suggests they are only moderately effective, have potential to cause significant harm and fail to address the biopsychosocial factors which may

underlie stress and distress (Banerjee 2009; Tampi *et al.* 2016). The preferred first-line treatment for stress and distress is now often considered to be a holistic assessment to identify unmet needs and non-pharmacological interventions, with antipsychotic use as a last resort (NICE 2018). Recent reviews suggest low to moderate efficacy of these non-pharmacological interventions. While this may be reflective of less high-quality research in non-pharmacological approaches, they are still preferable to medication as a first-line treatment due to their minimal adverse side effects and potential to address some of the underlying causes of stress and distress (Barton *et al.* 2016; Cabrera *et al.* 2014; Wang *et al.* 2019).

One rapidly growing area of non-pharmacological interventions is technology. The ever-increasing accessibility of technology has accelerated its use as an intervention in dementia care, with available applications at least doubling every five years (Ienca *et al.* 2017). Use of technology can range from adaptions to already widely used technologies such as games consoles (Dove & Astell 2019) and tablets (Evans *et al.* 2017) to specifically developed interventions such as social robots (Góngora Alonso *et al.* 2019) and assistive devices (Gibson *et al.* 2016).

Astell (2019), defines these applications as falling within four categories: 'diagnosis, assessment and monitoring'; 'leisure and activities'; 'maintenance of function'; and 'caregiving and management'. When considering the use of technology to address unmet needs which may lead to stress and distress, these will often fall within the leisure and activity category. This may include technology which facilitates the playing of games; communication with family and friends; increased accessibility to arts and music; providing comfort or enhancing existing interventions, such as reminiscence therapies.

There is currently evidence of technology use in the care of PLWD who have symptoms of stress and distress, although much of this is in the area of assessing or monitoring symptoms, such as door alarms or motion detectors. (Goerss *et al.* 2019; Qassem *et al.* 2014). These interventions are more concerned with managing care challenges than addressing the symptoms of stress and distress. There is, however, a growing research base in to technology which can be utilised to directly address the symptoms of stress and distress. These can include technologies which are accessed passively (such as pictures, films and music played through multimedia devices) or interactive technologies (such as computers, tablets, and robotic devices). There is tentative evidence that the use of tablets and touchscreen devices

can improve the psychological wellbeing of PLWD (Tyack & Camic 2017), however much of this research is still in the early stages of feasibility and small scale trials (Hitch *et al.* 2017).

Emerging, although limited, evidence also suggests that social robots may help to alleviate symptoms of depression in older adults, including PLWD, however, many of these studies are also at an early stage of research and unable to provide strongly convincing evidence (Chen *et al.* 2018). This limited evidence suggests that these social robots also have the potential to improve quality of life, promote mobility and reduce stress and agitation (Abbott *et al.* 2019; Góngora Alonso *et al.* 2019; Pu *et al.* 2019). A meta-analysis carried out by Leng et al. (2019) reviewed evidence from seven studies which suggested that animal-like robots can improve symptoms of stress and distress in PLWD, however, they reported that the evidence was limited by small, low-quality studies

The underlying mechanism by which technology can benefit PLWD experiencing stress and distress is still unclear. It has been suggested that some technologies may be able to meet some of the underlying unmet needs which lead to observed symptoms of stress and distress, such as the needs for occupation, attachment or comfort, (Kerssens *et al.* 2015), thereby improving symptoms of stress and distress. The method by which they do this and the needs which can be met by different modes of technology is, however, still poorly understood.

There has been significant interest in the literature regarding the potential of robotic interventions in dementia care; however, other technologies have also been utilised as interventions for stress and distress. There is not, to our knowledge, a review which examines the impact of a variety of technologies on a range of stress and distress symptoms. Additionally, current reviews often do not address the implementation of these interventions in real-world settings. This is particularly important given our understanding of stress and distress within biopsychosocial models and the need for interventions to account for a range of individual and systemic factors. Non-pharmacological interventions for stress and distress may also be more challenging to implement than pharmacological treatments (Wang *et al.* 2019), therefore it is prudent to address implementation when assessing the quality of evidence provided.

This review aims to assess the impact of a range of technological interventions on symptoms of stress and distress in PLWD.

Method

A protocol for the review was registered with PROSPERO (registration number CRD42019133883).

Search strategy

Searches were conducted in the PubMed; EMBASE, MEDLINE; PsycINFO; CINAHL; AMED; Global Index Medicus (GIM); Cochrane Library; ERIC; Scopus and Web of Science databases. Reference lists of included studies and relevant systematic reviews were also screened for relevant papers. A bespoke search strategy was developed for each database, using MESH or thesaurus terms (where available) relevant to the stated question. In databases where no thesaurus terms were available, such as Scopus and Web of Science, a keyword search was constructed as follows: Dementia AND("stress and distress" OR "behavio* and psychological symptoms of dementia" OR "neuropsychiatric symptoms of dementia" OR "psychological distress" OR “challenging behavio*”)AND (technolog* OR comput* OR robot* OR "information science" OR digital*).

Selection and screening

Inclusion Criteria

Studies were included if they met the following criteria:

1) a) The majority of participants had a diagnosis of dementia (confirmed or probable). Probable diagnoses were included as this is reflective of real care situations, where a person may require a stress and distress intervention without a confirmed diagnosis or where their dementia is suspected but has not been formally diagnosed.

   Or

   b) The participants were the family, carers (paid or unpaid) or staff members caring for a person / people with a confirmed or probable diagnosis of dementia, reporting on the PLWD’s symptoms.
2) The study utilised any empirical research method, comprising qualitative, quantitative and mixed-method studies of all methodologies from small-n case studies to randomised controlled trials. .
3) Technology which was accessed by a person with dementia (with or without the assistance of other people) was utilised as an intervention.
4) Symptoms were measured across at least two stress and distress symptom clusters. Studies which assess only one aspect of behaviour, affect, perception or thought

disturbance do not provide a sufficient measure of overall stress and distress (Dyer *et al.* 2018).

5) The study was published between January 2000 and January 2020, to keep the discussion of technology relevant to the technology available today and as a MEDLINE Trends analysis suggested the majority of studies of technology and dementia were published from the year 2000 onwards.
6) The study was published in English, as translation services were out with the scope of resources available to this study.

Exclusion Criteria

Studies were excluded if met the following criteria:

1) The study did not include a majority of PLWD as the population of interest
2) A technological intervention was not used.
3) The technological intervention was used solely by staff or carers or was utilised only as an alert system.
4) Technology was used solely as a delivery method for music therapy, simulated presence therapy or multi-sensory environments, as their effect on stress and distress symptoms has been reviewed elsewhere (Abraha *et al.* 2017; Lorusso & Bosch 2018; Pedersen *et al.* 2017).
5) The study only measured symptoms from one stress and distress symptom cluster.

After the removal of duplicates, studies were initially screened for relevance by title and abstract, with the eligibility of remaining studies assessed against the inclusion/exclusion criteria by analysis of the full text to determine which should be included.

Data extraction

Data extracted from accepted studies included the design and location of the study; size and demographics of the sample; dose and setting of technological intervention used; the target behaviour; outcome measure(s) used and a summary of the findings.

Appraisal process

A critical appraisal of each included study was carried out using the Joanna Briggs Critical Appraisal Tools (Joanna Briggs Institute 2017). Fifty per cent of the studies were reviewed by a second reviewer, with a consensus reached by discussion where necessary.

To understand how these interventions can be applied in 'real world' clinical settings, this review also appraised studies using the RE-AIM framework. RE-AIM assesses the Reach, Efficacy, Adoption, Implementation, and Maintenance in interventions both at individual and

organisational levels (Glasgow *et al.* 1999, 2019) and has been utilised across a wide range of intervention studies (Harden *et al.* 2015). The RE-AIM Model Dimension Items Checklist was used in this study (RE-AIM 2012). The second reviewer also carried out the RE-AIM analysis on fifty per cent of the studies, with a consensus reached by discussion where necessary.

Data synthesis

The heterogeneity of methodological approaches and measures in the studies prevented a meta-analysis from being carried out, and as such, a narrative synthesis of the included studies is presented.

Results

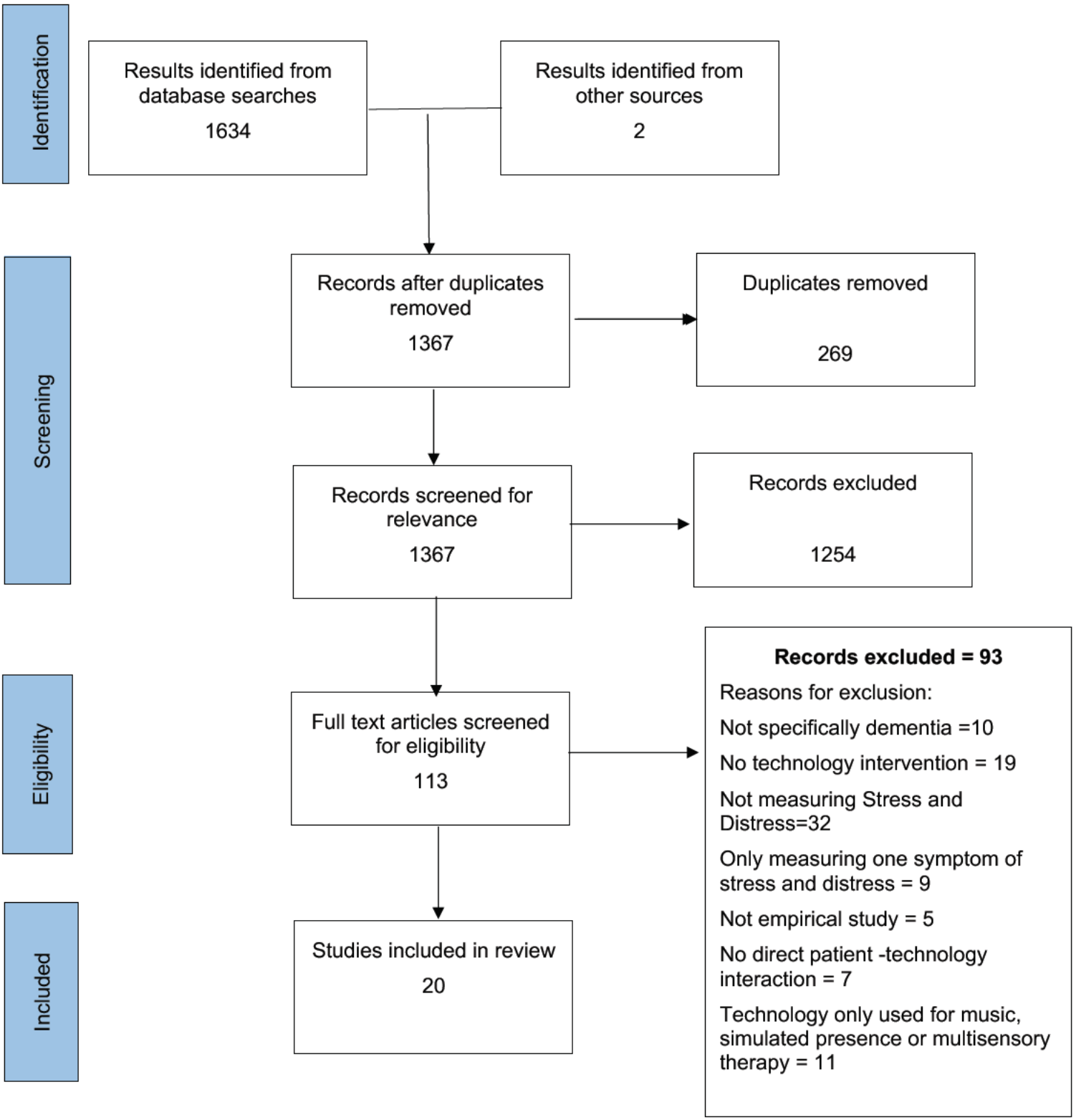
The search of relevant databases yielded 1634 records. Two further studies were identified from searches of relevant reviews and reference lists. After the removal of duplicates, 1367 articles remained to be screened by title and abstract, with 1254 excluded at this stage. Of the remaining 113 articles screened by examining the full text, 93 were excluded (the reasons for which are detailed in Figure 1), resulting in 20 studies eligible for inclusion in the review.

Characteristics of included studies

In total, 20 studies were included in the review. Two studies utilised multimedia films; five reported on tablet, touchscreen or computer devices; and thirteen utilised robotics. Three of the studies (Moyle *et al.* 2017, 2018a, 2019a) were drawn from the same randomised controlled trial. The number of participants in the studies ranged from 1 to 459, covering a total of 1142 PLWD, 57 carers and 32 staff members. The included studies provide a relatively international sample, with studies taking place in Australia (six studies) and the USA (five studies), with one study each from the UK, Japan, Spain, China, Sweden, Norway, New Zealand, Italy and Denmark. The studies were carried out in care homes/long term care facilities (seven studies); nursing homes (six studies); long term hospitals/secure dementia units (two studies); the community (two studies) and a day centre (one study). Two studies were carried out in multiple settings. The severity of dementia experienced by participants ranged from mild to severe, although some studies did not specify the severity or type of dementia.

Studies mostly measured stress and distress symptoms alongside other factors, such as ability in activities of daily living, quality of life and cognitive measures. A range of standardised outcome measures were used to quantify overall stress and distress.

Figure - 1 PRISMA Flow Diagram of records screened



The most common were: the Neuropsychiatric Inventory (NPI) (9 studies) which provides a measure of overall stress and distress; the Cohen Mansfield Agitation Inventory (CMAI) (7 studies) as a measure of the frequency of agitated behaviours and the Cornell Scale for Depression in Dementia (CSDD) (5 studies) as a measure of depressive symptoms. Seven studies utilised various forms of coded observation, while seven studies made use of qualitative methodologies. See Table 1 for study characteristics.

Findings of studies

Multimedia

Two studies investigated the effectiveness of multimedia film viewing on stress and distress symptoms. Both studies utilised individualised films, one of which featured favourite pictures, family greetings and preferred music (Hatakeyama *et al.* 2010) while the other utilised a biographical film of the individual's life (Francis *et al.* 2020). Both studies reported a significant reduction in overall stress and distress scores measured using the NPI, with Francis et al., (2020) reporting a large effect size (Cohen's d= 0.98). Numerical, but non-significant improvements in agitation and 'challenging behaviour', alongside carer reports of improvements in 'general wellbeing and compliance' are also noted.

Tablet/ touch screen / computer devices

Five studies utilised tablets, computers or touchscreen devices. Two studies provided participants with cognitive training exercises, and games (Rouse *et al.* 2019; Yu *et al.* 2015), one provided a reminiscence game (Yu *et al.* 2019) and two provided a range of programs, including games, videos, music, and web browsing (Davison *et al.* 2016; Loi *et al.* 2017). These studies provide mixed evidence for the efficacy of tablets, computers or touchscreen devices to improve overall stress and distress. Yu et al., (2015), Loi et al., (2017) and Rouse et al. (2019) reported improvements in overall stress and distress, ranging from small to large effect sizes (Cohen's d= 0.45-0.98); however, Yu et al., (2019) reported no significant change in overall stress and distress following a tablet-based intervention.

The evidence of the interventions impacting agitation is relatively weak in these studies. Loi et al., (2017) report significant improvement in agitation scores compared to controls, while Yu et al. 's (2015) touch screen cognitive training program study reported that agitation improved compared to the control group (Cohens d=0.45), but failed to find a significant difference between pre and post-intervention outcomes in either group. Davison et al. (2016) reported no significant difference in agitation.

The ability of the interventions to impact mood varied across studies, with evidence of a reduction in symptoms of depression (Davison *et al.* 2016), anxiety (Davison *et al.* 2016; Loi *et al.* 2017) and apathetic mood (Yu *et al.* 2019), alongside increased pleasurable affect (Rouse *et al.* 2019).

Robotics

Thirteen studies utilised robots as an intervention. Of these, nine utilised a robot seal called PARO (Jøranson *et al.* 2015; Lane *et al.* 2016; Liang *et al.* 2017; Marti *et al.* 2006; Moyle *et al.* 2017, 2018a, 2019a; Petersen *et al.* 2017; Thodberg *et al.* 2016); one utilised PARO and a humanoid robot, NAO (Valentí Soler *et al.* 2015); two used robotic cats: JustoCat (Gustafsson *et al.* 2015) and NeCoRo (Libin & Cohen-Mansfield 2004); and one a robotic teddy bear (CuDDLer) (Moyle *et al.* 2016). Thodberg et al. (2016) utilised PARO as a control group against the intervention of therapy dog visits, while the other twelve studies utilised the robots as the primary intervention.

Only seven of the robotics studies measured overall stress and distress. Valentí Soler et al., (2015) found a decrease in overall stress and distress from baseline to follow up in their humanoid robot trial in a day centre setting, but other robot and setting groups in this study showed no significant difference in overall stress and distress. Qualitative studies highlighted a reduction in overall stress and distress from staff member reports (Moyle et al., 2018) and of PLWD showing improved agitation, mood and engagement from family reports (Moyle *et al.* 2019a). Lane et al., (2016) noted a decrease in negative behaviours and an increase in positive behaviours following their PARO intervention, while Marti et al., (2006) presented observational reports of reduced stress, increased positive emotion and connection following their intervention with the same robot. However, Liang et al., (2017) reported no significant difference in overall stress and distress in their PARO intervention and Thodberg et al., (2016) found an increase in overall stress and distress across all groups, regardless of intervention.

The evidence of the impact of robotic interventions on agitation is mixed in the included studies. Two studies note significant improvement in agitation when compared to controls (Jøranson *et al.* 2015; Petersen *et al.* 2017), and two qualitative studies provide reports from staff and family members of reductions in agitation (Moyle *et al.* 2018a, 2019a). Gustafsson et al., (2015) found that two out of four participants had improvement in agitation in their small study, while the largest RCT in the review reported no change in the standardised agitation measure but did report a reduction in agitation in video observations compared to controls, with a small effect size (Moyle *et al.* 2017). Liang et al., (2017) however found no significant change in agitation level while Libin & Cohen-Mansfield, (2004) reported a decrease in control group agitation, but not in the group exposed to the robot. Moyle et al. (2016) reported that

their small n study found 4 out of 5 patients experienced an increase in agitation during the course of the study.

Robotics studies also suggest that an increase in pleasure (Gustafsson *et al.* 2015; Libin & Cohen-Mansfield 2004; Moyle *et al.* 2017) and a reduction in depressive symptoms (Jøranson *et al.* 2015; Petersen *et al.* 2017) were the most notable affect changes due to the intervention. Several studies noted more ambiguous affect improvements, such as an increase in positive patient states (Lane *et al.* 2016), more positive than negative emotions in response to the intervention (Moyle *et al.* 2016) and qualitative reports from family members of improved mood in the PLWD(Moyle *et al.* 2019a). Liang et al. (2017) reported more positive facial expressions in the PARO group and also found depression measure improvements at six weeks; however, scores deteriorated at 12 weeks. The authors believe this may be due to the removal of PARO at the end of the intervention period. Valentí Soler et al., (2015) reported that in their nursing home setting, both NAO and PARO decreased apathy, but PARO also increased irritability and disinhibition, while irritability decreased in the day centre with the same intervention. Thodberg et al. (2016) found a decrease in depression across all groups, regardless of intervention.

Table 1 - Summary of included studies

Author, Year & Country	Study description	Sample size & Type of Dementia	Setting	Type of Technology	Control Group(s)	Frequency & Duration	Stress & Distress outcome measures & symptoms	Stress and Distress symptom results
MULTIMEDIA STUDIES								
Francis et al (2020) UK	Mixed method feasibility study	n= 11 PLWD n= 4 formal carers Moderate to severe AD=5 VaD= 3 Mixed = 1 Parkinson's dementia = 1 unknown = 1	Residential care home	Biographical film of individuals life	N/A	30 min 2-4 x per week For 24 weeks	NPI-NH - Overall stress and distress CBS - Challenging behaviour CMAI - Agitation Formal carer focus group - Overall stress and distress	Significant reduction in NPI-NH scores ES=0.98 Numerical but non-significant improvements in CMAI & CBS Carer themes: included perception of participant change, in 'general wellbeing and compliance'
Hatakeyama et al (2010) Japan	Between groups pilot study	n=28 Treatment group n=13 Control n =15 Moderate to severe AD, VaD or mixed	Long term care hospital	DVDs of favourite pictures, family greetings, and / or preferred music	Standard Care	2 hours every day for 4 weeks	NPI - Overall stress and distress	Significant reduction in NPI score in treatment group form 26(±12) to 17(±11)

Table 1 - Summary of included studies

Author, Year & Country	Study description	Sample size & Type of Dementia	Setting	Type of Technology	Control Group(s)	Frequency & Duration	Stress & Distress outcome measures & symptoms	Stress and Distress symptom results
TABLET/ TOUCH SCREEN / COMPUTER DEVICE STUDIES								
Davison et al (2016) Australia	Randomised cross over study	N=11 Mild to severe dementia	Nursing home	Touch screen device with personalised photographs, movies, messages and music	Social control condition- reading newspaper with staff member	4 weeks	CMAI - Agitation RAID - Anxiety CSDD - Depression	Significant reduction in CSDD and RAID in intervention group. No significant change in CMAI No significant changes in control group outcomes.
Rouse et al (2019) USA	Repeated measures pilot study	N=10 High social interaction n=5 Low social interaction n=5 Mild to moderate dementia	Adult day centre	Computer based interactive cognitive training games in high and low social settings	N/A	3 sessions per week for 12 weeks	NPI - Overall stress and distress OME - Overall stress and distress	Significant decrease in NPI score, (ES=0.53), social interaction level was not significant. OME reports participants mostly attentive, with observed pleasurable affect during intervention.

Table 1 - Summary of included studies

Author, Year & Country	Study description	Sample size & Type of Dementia	Setting	Type of Technology	Control Group(s)	Frequency & Duration	Stress & Distress outcome measures & symptoms	Stress and Distress symptom results
Yu et al (2015) China	RCT	n= 32 Intervention n=16 Control group n=16 Mild to moderate dementia	Community	Touch screen cognitive training games	Conventional cognitive training	30 min x 8 sessions over 4-8 weeks	NPI - Overall stress and distress CSDD - Depression CMAI - Agitation	Reduction in total NPI score (ES=0.45) in intervention group. Intervention group improved CMAI significantly more compared to control (ES=0.84) but no significant difference pre-post in either group No CSDD change in either group
Yu et al (2019) USA	Randomised Pilot study	N=80 Group intervention n= 32 Individual intervention n=32 Control n=16 Dementia diagnosis, type unspecified	Community	Tablet based reminiscence game	Waitlist control	30 min 2x per week for 6 weeks + 6 weeks patient directed use	AMS -Mood NPI-Q - Overall stress and distress	Group intervention significantly decreased apathetic mood compared to control Improved social interaction in individual group at 6 weeks, improvement was lost at 12 weeks No significant change in NPI-Q

Table 1 - Summary of included studies

Author, Year & Country	Study description	Sample size & Type of Dementia	Setting	Type of Technology	Control Group(s)	Frequency & Duration	Stress & Distress outcome measures & symptoms	Stress and Distress symptom results
Loi et al (2017) Australia	Non-blinded, non-randomised crossover study	N=15 N=7 patients with dementia, type unspecified	Residential Aged Care Facility	iPad touch screen tablets with commercially available apps	Standard care and reading newspaper with staff member	10 minutes 3x per week for 3 weeks	NPI-NH - Overall stress and distress Staff perspective questionnaire - Overall stress and distress	Significant decrease in NPI overall, agitation and anxiety scores, compared to controls and standard care Staff members mostly neutral about participant behaviour improvement, but believe they have benefited from intervention
ROBOTIC STUDIES								
Gustafsson et al (2015) Sweden	Mixed methods Pilot study in two stages	Quantitative single case n=4 PLWD Qualitative interview study n=14 (11 staff, 3 relatives) Dementia diagnosis, type unspecified	Care home	Plush Robot (Justocat)	Individual baseline	7 week intervention	CMAI - Agitation Qualitative interview - Well-being/affect	50% of participants had a mean increase in CMAI (qualitatively reported as positive increase in activity); 50% showed very minimal decrease Qualitative results suggest perceived increase in interaction and pleasure

Table 1 - Summary of included studies

Author, Year & Country	Study description	Sample size & Type of Dementia	Setting	Type of Technology	Control Group(s)	Frequency & Duration	Stress & Distress outcome measures & symptoms	Stress and Distress symptom results
Jøranson et al (2015) Norway	Cluster RCT	N=60 Intervention n=30 Control n =30 Mostly Moderate to severe dementia (1 cognitive impairment)	Nursing homes	Plush Robot (PARO)	Standard Care	30 min 2x per week for 12 weeks	BARS - Agitation CSDD - Depression Medication usage	Significant difference in effect estimate between intervention and control groups from baseline to follow up in BARS and CDSS. Agitation and depression both reduced in intervention group Medication changes were not significant between the groups
Lane et al (2016) USA	Repeated measures pilot study	N=23 82% had dementia diagnosis	Long term care facility	Plush Robot (PARO)	N/A	18 month study period Observation of at least 5 minutes interaction with intervention	Observation of behaviour and mood - Behavioural & Mood states	Significant decrease in negative behaviours post-intervention Significant increase in positive behaviours post-intervention Significant increases in positive patient states including calmness and bright affect.

Table 1 - Summary of included studies

Author, Year & Country	Study description	Sample size & Type of Dementia	Setting	Type of Technology	Control Group(s)	Frequency & Duration	Stress & Distress outcome measures & symptoms	Stress and Distress symptom results
Liang et al (2017) New Zealand	Pilot RCT	N= 30 care dyads (PLWD+ carer) Intervention group n=15 dyads Control group n=15 dyads Dementia diagnosis, type unspecified	Day care centre (delivered as a group intervention) and home setting (delivered as individual intervention)	Plush Robot (PARO)	Standard Care	In care setting: 30 min group session 2-3 times per week for 6 weeks At home: as desired	Time sampling observation (care setting) -Behaviour & Affect Cortisol &Blood pressure - Physiological stress CMAI-SF - Agitation CSDD - Depression NPI-Brief - Overall Stress and distress Qualitative reports from caregivers (home setting) - Overall Stress and distress	PARO group significantly more positive facial expressions & engaged in conversation more compared to control. CSDD score significantly improved at 6 weeks, but deterioration at 12 week follow up (possibly due to removal of intervention) No other outcomes were significantly different

Table 1 - Summary of included studies

Author, Year & Country	Study description	Sample size & Type of Dementia	Setting	Type of Technology	Control Group(s)	Frequency & Duration	Stress & Distress outcome measures & symptoms	Stress and Distress symptom results
Libin & Cohen-Mansfield (2004) USA	Repeated measures pilot study	N=9 Moderate to Severe Dementia	Nursing home	Plush Robot (NeCoRo Cat)	Non- Robotic Plush toy cat	One 10 minute session per day of each condition in randomised order	ABMI - Agitation LMBS - Behaviour Attitude, attention, intensity and duration observation – Engagement & Affect	Physical and overall agitation significantly decreased in control group. No significant difference in intervention group agitation. Intervention significantly increased pleasure and interest, control did not. No significant difference in engagement
Marti et al (2006) Italy	Exploratory ethnographic study	N=1 Moderate Dementia	Nursing Home	Plush Robot (PARO)	N/A	6 months	Direct observation - Overall stress and distress Video observation - Overall stress and distress NPI (pre-only) - Overall stress and distress	Observational reports suggest intervention reduced stress, induced positive emotions and allowed an emotional connection with caregivers to develop

Table 1 - Summary of included studies

Author, Year & Country	Study description	Sample size & Type of Dementia	Setting	Type of Technology	Control Group(s)	Frequency & Duration	Stress & Distress outcome measures & symptoms	Stress and Distress symptom results
Moyle et al (2016) Australia	Feasibility Case study	N= 5 Mild to moderate dementia AD=3 Young onset =1 Unknown =1	Nursing Home	Plush Robot (CuDDler)	N/A	30 min 3x per week for 5 weeks	CMAI - Agitation Coded video observation using OERS - Emotional response Semi structured interview - Engagement	4/5 participants experienced an increase in CMAI during intervention period Participants demonstrated more positive than negative emotions in response to intervention Range of engagement – poor to moderate but overall limited positive impact of intervention on engagement
*Moyle et al (2017) Australia	Cluster RCT	N=459 Intervention n= 157 Control (plush toy) n=156 Control (standard care) n = 146 Various Dementia diagnoses	Long term care facility	Plush robot (PARO)	Non- Robotic plush toy and Standard Care	15 min 3x per week 10 weeks	Video observation - Engagement & Mood CMAI-SF - Agitation	Greater verbal and visual engagement in intervention compared to plush toy control (ES=0.29-0.61). Increased pleasurable mood in intervention compared to standard care control (ES=0.2) Reduction in observed agitation in intervention compared to standard care (ES= 0.12) No significant change in CMAI-SF across groups.

Table 1 - Summary of included studies

Author, Year & Country	Study description	Sample size & Type of Dementia	Setting	Type of Technology	Control Group(s)	Frequency & Duration	Stress & Distress outcome measures & symptoms	Stress and Distress symptom results
*Moyle et al (2018) Australia	Qualitative study (nested in RCT)	N= 10 (staff)	Long term care facility	Plush Robot (Paro)	Non- Robotic plush toy	15 min 3x per week 10 weeks	Qualitative semi structured interviews with staff - Overall stress and distress	Staff reported intervention was useful in reducing agitation, restlessness, wandering and overall stress and distress. Staff from control condition did not identify meaningful benefits.
*Moyle et al (2019) Australia	Qualitative (nested in RCT)	N= 20 family members	Long term care facilities	Plush Robot (PARO)	Non- Robotic plush toy or Standard Care	15 min 3x per week 10 weeks	Qualitative semi structured interviews with family members - Overall stress and distress	Families reported intervention reduced agitation, improved mood and increased engagement Control group family members did not perceive control to bring significant benefits
Petersen et al (2017) USA	Repeated measures randomised block design	N= 61 Intervention n= 35 Control (n= 26 Mild to moderate dementia	Secure dementia units	Plush robot (PARO)	Standard Care	20 min 3x per week	RAID - Agitation CSDD- Depression GDS(1) - Global deterioration Medication use	RAID score, CSDD score, pulse rate and pain & behavioural medication use all reduced significantly in intervention group compared to control group No difference in global deterioration or sleep and depression medication.

Table 1 - Summary of included studies

Author, Year & Country	Study description	Sample size & Type of Dementia	Setting	Type of Technology	Control Group(s)	Frequency & Duration	Stress & Distress outcome measures & symptoms	Stress and Distress symptom results
Thodberg et al (2016) Denmark	Randomised block design study	N=100 Real dog intervention=35 Control (PARO)n=35 Control (Plush toy) n=30 Minority diagnosed, ~ 30%, but all presumed dementia	Nursing Homes	Plush Robot (PARO) used as control	Real dog visits (intervention) and Non-robotic plush toy cat (control)	10min 2x per week for 6 weeks	GBS - Overall stress and distress GDS(2) - Depression Actigraphy sleep data - Sleep	Increase of GBS and decrease in GDS across all groups No sleep difference at follow up No differences between groups in any measures at follow up
Valenti Soler et al. (2015) Spain	Two phase pilot study split over two settings	Phase 1 n = 101 Phase 2 n = 110 Mild to severe dementia	Nursing home and day centre	**Nursing home** Phase 1: Humanoid robot (NAO); Plush Robot (PARO); control Phase 2: Plush Robot (PARO); Real Dog; Control **Day Centre**	Real Dog visits or conventional therapy	30-40 min, 2 x per week for 3 months	GDS(1) - Global deterioration NPI - Overall stress and distress APADEM-NH - Apathy AI- Apathy	**NURSING HOME** **Phase 1:** GDS- Increased across all group NPI- overall no significant difference between groups. However, delusion item scores increased in NAO group; apathy item scores decreased in NAO group & irritability item scores increased in PARO group APADEM-NH- significant decrease in NAO & PARO groups **Phase 2:** GDS- Increased across all group NPI- overall no significant

Table 1 - Summary of included studies

Author, Year & Country	Study description	Sample size & Type of Dementia	Setting	Type of Technology	Control Group(s)	Frequency & Duration	Stress & Distress outcome measures & symptoms	Stress and Distress symptom results
				Phase 1: Humanoid robot (NAO) Phase 2: Plush Robot (PARO)				difference between groups. However increase in hallucination and irritability items in PARO and Dog groups compared to control. Disinhibition item scores increased in PARO group compared to the Dog group. Night-time disturbance decreased in PARO group compares to dog group **DAY CENTRE** **Phase1 (NAO):** GDS- Increased from baseline to follow up NPI- decrease in irritability and total NPI from baseline to follow up **Phase2(PARO)**: GDS- Increased from baseline to follow up

* denotes art c es der ved from the same random sed contro tr a

ABMI = Ag tated Behav ours Mapp ng Instrument; AD= A zhe mer's Dement a; AI = Apathy Inventory; AMS= A zhe mer's D sease and Re ated Dement a Mood Sca e; APADEM NH = Apathy Sca e for Inst tut ona sed Pat ents w th Dement a Nurs ng Home; BARS= Br ef Ag tat on Rat ng Sca e; CBS= Cha eng ng Behav our Sca e; CMAI= Cohen Mansf e d Ag tat on Inventory; CMAI SF= Cohen Mansf e d Ag tat on Inventory Short Form; CSDD= Corne Sca e for Depress on n Dement a; ES=effect s ze; GBS = Gottfr es Brane Steen Sca e dement a symptoms sca e; GDS(1)= G oba deter orat on sca e (ncreased score = deter orat on); GDS(2) = Ger atr c Depress on sca e; LBMS =Lawton's Mod f ed Behav our Stream; NPI = Neuropsych atr c Inventory; NPI Br ef = Neuropsych atr c Inventory Br ef vers on; NPI NH = Neuropsych atr c Inventory Nurs ng Home; NPI Q = Neuropsych atr c Inventory Quest onna re Careg ver; OERS = Observed Emot ons Rat ng Sca e; OME= Observat ona Measurement of Engagement; PLWD = peop e v ng w th dement a; RAID = Rat ng for Anx ety nn Dement a; RCT = Random sed contro ed tr a ; VaD= Vascu ar Dement a; VC IOE =V deo Cod ng Protoco Incorporat ng Observed Emot on

Three studies reported on behavioural and perceptual changes following robot interventions. Valentí Soler et al. (2015) found PARO reduced night-time disturbance but increased hallucination scores in their nursing home setting. Gustafsson et al. (2015) reported qualitative data from carers of a perceived increase in social interaction during robotic intervention while Petersen et al. (2017) found a reduction in behavioural medication use compared to controls.

Quality of papers

A full summary of the results of the critical appraisal of studies is shown in Appendix B. The overall quality of the included RCTs was low to moderate, with six of the ten RCTs meeting at least 50% of the applicable quality criteria. Blinding criteria were judged not to be applicable in these studies, as blinding participants or those delivering the interventions would not be feasible. Follow up analysis was incomplete or insufficient in all studies. Quasi-experimental studies were generally of moderate quality, with all studies meeting greater than 50% of the quality criteria, although none included an independent control group. Qualitative studies or the qualitative elements of mixed-method studies were generally of moderate quality, with six of seven studies meeting greater than 50% of the applicable criteria. No studies, however, addressed the influence of the researcher on the research. The case series and case report studies were generally of low quality, with one of the three studies meeting 50% of the applicable quality criteria.

RE-AIM analysis

A full summary of the RE-AIM analysis of studies is shown in Appendix C. The RE-AIM analysis assesses the reach, effectiveness, adoption, implementation and maintenance of the interventions described in the studies.

Reach was at least partially reported in 60% of the studies. Characteristics of participants compared to non-participants and the use of qualitative methods to understand each were not reported in any of the included studies. *Effectiveness* was addressed, at least partially in all of the included studies, with all studies reporting a primary outcome measure and 80% of studies reporting at least one secondary outcome measure. Only one study (Petersen *et al.* 2017) addressed robustness across subgroups. *Adoption* was relatively poorly reported in the included studies, with only 40% of studies reporting at least one adoption factor. Comparison of participating settings compared to non-participating settings; the percentage of staff invited to participate; and characteristics of staff participants compared to non-participating staff were all poorly reported. *Implementation* was partially reported in 45% of the included studies, with adherence and clarity of adaptions to interventions the most poorly reported elements. *Maintenance* was the most poorly reported RE-AIM factor, as only 10% of studies reported on at least one element. None of the studies reported elements addressing maintenance at the individual level, and those which did address setting level maintenance (Moyle *et al.* 2018a, 2019a) did so only fleetingly.

Discussion

The use of technology as an intervention for stress and distress in dementia is particularly pertinent at present. The drive for technological approaches to care is accelerating, driven by widespread accessibility and the use of technological interventions in dementia receiving increasing attention in the mainstream press (BBC News 2019; Kalb 2020). The benefit of technology often being easily accessible and its face validity, however, also poses the potential difficulty of it being used without a strong evidence base. Therefore, this study aids our understanding of the interpretation and implementation of evidence from the current literature on a range of technology-based non-pharmacological interventions for stress and distress in care settings.

Our findings suggest that robots may be a beneficial intervention in overall stress and distress, and there are certainly positive qualitative reports of this; however, the quantitative measures used in the included studies were less clear of the benefit of the robots. Other reviews in the area of robotic interventions for stress and distress report similar findings; these interventions demonstrate potential to influence stress and distress positively, but low-quality studies and heterogeneity of definitions for stress and distress mean significant caution is needed in our interpretation of these results (Leng *et al.* 2019; Pu *et al.* 2019).

Conflicting reports of the impact of robotics on agitation also suggest that while there may be some efficacy, some studies report no effect or even an increase in agitation, with this conflict evident in reports from meta-analyses. Leng *et al.* (2019) reported statistically significant improvements in agitation from robot interventions in their meta-analysis, while Pu *et al.'s* (2019) meta-analysis of the same studies reported no difference in agitation. Moyle *et al.* (2019b) highlight the need for frequent assessment and individual support plans for PLWD using these interventions, as there is some evidence that robots may increase agitation, a factor that should be considered in future studies.

Evidence from included studies using tablet, touchscreen or computer devices also reported mixed results. Similar to robotic interventions, they may be most efficacious in improving affect but are limited in the evidence of improvement in overall stress and distress or agitation. Hitch *et al.* (2017) also found evidence for the impact of tablet devices in stress and distress to be limited in their review, although Upton *et al.* (2011) reported that use of tablets increased interpersonal interactions and positive social environments, which may be factors in mediating stress and distress.

Studies in the current review, which utilised multimedia interventions, report reductions in overall stress and distress symptoms but with small sample sizes (n=39 across two studies)

and low to moderate quality. The application of the multimedia interventions varied across the studies and therefore, more in-depth evidence as to the optimal content and presentation is required before the potential benefits of these interventions can be fully understood.

The way in which technology alters symptoms of stress and distress in PLWD is not fully understood, and it may be that the active components vary between different types of technology. Technology-based non-pharmacological interventions can often offer meaningful activity which increases positive affect and potentially results in improvements in stress and distress (Swan *et al.* 2018). Robotic interventions have been shown to have psychological (Mordoch *et al.* 2013) and physiological (Robinson *et al.* 2015; Wada & Shibata 2007) calming effects which may influence agitation and anxiety associated with stress and distress. Robots have also been hypothesised to meet attachment needs for some people with dementia (Hung *et al.* 2019; Libin & Cohen-Mansfield 2004), thereby potentially addressing unmet needs which underlie stress and distress. Robotic and tablet interventions also support increased social interaction which is known to have a significant impact on mood in people with dementia (Beerens *et al.* 2018). Although the studies included in this review suggest some efficacy in improving stress and distress symptoms, the beneficial components of each technological intervention have only been hypothesised, which emphasises the need for future studies to consider not only which aspects of technology may be beneficial, but also how this relates to our understanding of stress and distress symptoms as an expression of unmet need. Future studies may consider isolating components of technological interventions (e.g. interactive vs. passively consumed or screen-based vs real-world objects) to identify if some are better at meeting the needs of PLWD than others. They may also consider identifying which needs are more easily met with technological interventions and which may be more difficult to influence in this way.

Studies which included participants with probable or suspected dementia were included in this review to account for some of the challenges faced in typical care settings, however, this is somewhat problematic when attempting to draw conclusions about a specific population of PLWD. Future studies would benefit from clearer screening and reporting of the type, severity and functional abilities of those included in studies. This would allow for greater comparison of the effectiveness of different technological interventions at various stages of dementia, and integration of this with the literature which considers the ethical and practical appropriateness of various interventions at differing stages of the illness.

Studies were carried out across a relatively broad range of settings; however, none of the included studies took place in acute inpatient facilities, which limits the conclusion which can be drawn about the impact of these interventions in such settings where the application of non-pharmacological interventions is particularly challenging (White *et al.* 2017). This also

poses a broader question of other critical systemic factors, such as the role of staff and caregivers in delivering these interventions, which are largely overlooked in most studies (Lawrence *et al.* 2012; Wang *et al.* 2019). Many of the studies in this review presented the technological intervention to participants in a group setting and utilise standardised measurement scales, an approach which has been described as "frequently irrelevant and even unhelpful" (Kerssens *et al.* 2015. p. 95) when considering the greatly varying needs and experiences of PLWD. The heterogeneity of stress and distress and a failure by the majority of studies in this review to consider individual outcomes may partially explain the wide ranging and at times conflicting results obtained from the studies. More insightful results may be obtained from future studies which focus on methodologies with person-centred, individually targeted outcome measures which account for the needs and characteristics of the individual, such as Dementia Care Mapping (Bradford Dementia Group 2005).

The focus on robotics studies in the literature provides us with an emerging evidence base in these interventions, but other technological interventions are less well researched in their application to stress and distress symptoms. One particular concern with specially designed robots is their relative cost when compared to other pre-existing technological options such as tablets or multimedia displays. PARO robots, for example, currently retail for approximately £5000. (PARO Seal 2020) compared to commercially available tablets which can be priced from hundreds of pounds. Only two studies included in this review utilised mainstream hardware and software requiring no specialist adaption. There is evidence from other areas of dementia research that current widely available technology can be applied in dementia care settings, such as the use of games consoles (Dove & Astell 2019) or off-the-shelf tablets(Evans *et al.* 2017; Hitch *et al.* 2017; Swan *et al.* 2018; Upton *et al.* 2011), yet there is less evidence of this in the treatment of overall stress and distress.

The terms and definitions used to describe stress and distress can make comparison across studies difficult (Linde *et al.* 2014). Given the significant investment in both technology and staff training required to implement new technology in a dementia care setting efficaciously, those investing in these interventions are likely to be drawn more to those interventions which can provide benefit across a range of stress and distress symptoms. It is therefore important not only to understand an intervention's impact on one specific symptom but also on overall stress and distress. Several of the included studies utilised video observations of behaviour as a useful tool to assess individual change in overall stress and distress alongside standardised scales. Clear coding protocols are, however, required to ensure the methods are reliable (Moyle *et al.* 2019b). The use of more qualitative or mixed-method studies in future, particularly those which prominently feature the PLWD's voice, may also help clarify where true changes to stress and distress are made.

The RE-AIM analysis in this review highlights several challenges in translating research findings of technology in stress and distress to clinical interventions that can be applied on a broad scale. Our RE-AIM analysis is consistent with results found in reviews of both psychosocial interventions for stress and distress (Boersma *et al.* 2015) and the literature as a whole (Glasgow *et al.* 2019); that adoption and maintenance factors are chronically under-reported. It should be noted that although no single paper in this review addressed over 50% of RE-AIM factors, the RCT by Moyle and colleagues (2017), when read alongside subsequent publications from the same trial (Jones *et al.* 2018; Mervin *et al.* 2018; Moyle *et al.* 2019a, 2019b, 2017, 2018b), provide a relatively thorough report of a majority of RE-AIM factors.

Adoption is particularly important when considering non-pharmacological interventions, as the impact of the setting and staff on the outcome of the interventions is likely to be much greater than in pharmacological studies (Wang *et al.* 2019). While the technological intervention may be used independently, staff have the potential to influence, both positively and negatively, how it is received, utilised and the longevity of its application (Lawrence *et al.* 2012). The studies in this review largely failed to consider the significance of staff's experiences of using the technology, with very little understanding as to any potential positive or negative impact of the interventions on staff themselves. The resources available to, and professional backgrounds of the staff implementing these interventions are also likely to impact how frequently interventions are empirically tested and published, with potential consequences for the whole evidence base of non-pharmacological intervention adoption.

Maintenance is also a critical factor in these studies, given that the potential cost of technological applications is likely to be prohibitive unless they can be maintained to provide long term benefits. There is also the potential for technological interventions, particularly those which are innovative, such as robotics, to have a strong “novelty” factor, which may mean they do not produce the desired effect in the longer term (Moyle *et al.* 2017; Swan *et al.* 2018). A follow-up study from Moyle and colleagues' 2017 RCT found that the robot PARO did not represent a cost-effective intervention for agitation when compared with a plush toy in the short term (Mervin *et al.* 2018); however, further research is required to determine the cost-effectiveness of technological interventions for overall stress and distress in the longer term. There may be ongoing costs of software upgrades, staff training and replacement of hardware alongside challenges of habituation to the intervention to consider. Future studies should seek to determine the feasibility of maintaining these interventions in the long term, not only in terms of continued clinical benefit but also integration into usual care and cost-effectiveness.

The studies in this review highlight several challenges in the implementation of technological interventions for stress and distress. The need for flexible implementation strategies which continue assessment and evaluation throughout the use of the intervention has been identified both in the broader use of non-pharmacological interventions for stress and distress (Boersma *et al.* 2015) and specifically for the use of technology (Moyle *et al.* 2019b). This allows for the identification of possible adverse effects of the intervention on the PLWD, as they are certainly not suitable for all (Birks *et al.* 2016). The need for varying implementation strategies dependant on a PLWD's presentation should also be considered, as differing levels of agitation may impact engagement (Jones *et al.* 2018), and individuals may respond differently to interventions at different time points (Moyle *et al.* 2019b). Given the understanding of stress and distress symptoms as an expression of unmet need, the true test of effective implementation of an intervention in this area will be if it can successfully be applied and adjusted to meet a particular need. Unfortunately, the evaluation of the interventions in these studies do not provide a clear link between interventions and the needs which they may be meeting. A more person-centred approach, with individual technological intervention care plans and outcome measures in future research may better help us to understand the real potential of these interventions.

Strengths and Limitations of this review

The strengths of this review include the inclusion of a range of different technologies and the use of the RE-AIM framework assessing the implementation of interventions. There are also limitations to this review. Limiting the studies included to those which measure at least two aspects of stress and distress may have excluded studies which still have relevance to the broader discussion of the role of technology in stress and distress. The inclusion of studies in which some participants did not have a formal diagnosis of dementia may also limit the conclusions which can be drawn about the impact of the interventions on PLWD. This study did not seek to include grey literature and was unable to include articles published in a language other than English.

Future recommendations

There is a need for future research to strengthen, but also diversify the literature base with studies which acknowledge the need for more person-specific application of interventions and examine overall stress and distress, not just individual symptoms. Analysis of the active components of technological interventions and a greater understanding of why they produce benefit for PLWD would also be an important focus for future studies. In doing so, they may be more able to link the impact of technological interventions to biopsychosocial models of stress and distress and specific unmet needs. This could be achieved through studies which focus on more targeted, person-centred methodologies and outcome measures, such as

single-n case series, greater use of behavioural observational methods such as Dementia Care Mapping and the isolation of specific components of technological interventions. These studies should also aim to include readily available technology as well as more novel approaches and to compare and contrast technological interventions on efficacy and applicability in 'real world' settings. Attention is also needed on implementation factors, particularly adoption and maintenance over longer follow-up phases. Inclusion of systemic factors, such as the impact of staff capabilities and attitude on the delivery of interventions, will also be important in future studies. The accessibility of technological applications compared to some other non-pharmacological interventions makes it likely that technology use in dementia care settings is likely to continue increasing at a rapid pace. Ienca et al. (2017) identified over 500 intelligent assistive technologies with potential application to dementia care, although just over 50% of these had undergone some form of clinical validation. The challenge to the research community will be to keep pace with these advances to ensure applications of technology are evidentially robust and that their application and implementation can be carried out in the most efficient, yet person-centred way.

Conclusion and Clinical Implications

There is potential for technology-based non-pharmacological interventions to reduce stress and distress; however, the quality and breadth of the literature to date means these findings should be noted with caution. Further research is necessary to understand which technologies are likely to be most beneficial for people with dementia and how they can meet the needs of PLWD experiencing stress and distress. Those utilising technology-based non-pharmacological interventions for stress and distress in clinical settings should ensure they use flexible implementation models which adapt to the person, their presentation and their unmet needs throughout the intervention to ensure these technologies are used within a responsive, person-centred approach.

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Authors Roles

F. Beaton and A. Guzman designed the study. F Beaton carried out the systematic review and wrote the initial draft of the manuscript. F. Beaton, A. Guzman and G. Bowie were involved in the critical revisions of the manuscript. D. Holly acted as the additional reviewer for quality and RE-AIM analyses.

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Chapter 2 – Empirical Study

A mixed-method multiple-baseline single-case study exploring the impact of the Tovertafel (Magic Table) on factors impacting staff burnout in an acute dementia care hospital ward.

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Abstract

Objective: To assess the impact of the Tovertafel, a technology-based non-pharmacological intervention on factors of staff burnout, sense of competence and reciprocity.

Design: A mixed-method multiple-baseline single-case study methodology was used.

Setting: An acute, dementia care, admission ward in a rural Scottish health board.

Participants: 15 nursing and Health Care Assistant staff members.

Intervention: The Tovertafel (meaning Magic Table in Dutch) uses digital projection and infra-red detection to provide an interactive and playful recreation activity for people with dementia. Participants can engage with the Tovertafel's many games designed specifically for people with dementia.

Measurements: Individual outcome items were selected from the Abbreviated Maslach Burnout Inventory (aMBI), Sense of Competence in Dementia Care Staff (SCIDS) Scale and the Jeffcott Reciprocity Questionnaire. A bespoke shift-by-shift measure of staff satisfaction was also used, alongside a qualitative questionnaire of staff experience.

Results: 11 participants returned sufficient data for analysis. A Percentage-All Non-overlapping Data (PAND) analysis suggested 31 of the 45 individual outcome items improved over the course of the study. The meta-analysis found that individual outcome items demonstrated small to medium effect sizes across participants. A thematic analysis of the staff experience questionnaire established three themes: patient's positive engagement and response to the Tovertafel; benefits to staff from using the Tovertafel; and opportunities to enhance care with no changes to normal workload. The PAND and meta-analysis of the shift by shift measure of staff satisfaction measure suggested no effect across participants over the course of the study

Conclusions: The Tovertafel has the potential to improve burnout factors for some staff and improve staff/patient relationships without additional burden to staff. The results from this study were obtained in a busy, acute care dementia ward, suggesting that future studies in other settings may also find the Tovertafel to be beneficial to staff.

Keywords: Dementia; staff; burnout; technology; intervention; non-pharmacological; hospital ward

Introduction

Non-pharmacological interventions play an important and meaningful part in dementia care (Barton *et al.* 2016; Wang *et al.* 2019). In Scotland, health policies, such as the National Clinical Strategy for Scotland (The Scottish Government 2016) and The Technology Charter for People Living with Dementia in Scotland (Alzheimer Scotland *et al.* 2015) highlight that technology can be utilised to deliver these interventions to support the physical and mental wellbeing of people living with dementia. Ever-increasing availability of technology makes these interventions even more accessible (Astell 2019; Ienca *et al.* 2017); however, the potential impacts of these interventions on staff are often not addressed. Staff can be essential to the successful implementation of such interventions (Lawrence *et al.* 2012) and factors affecting their capabilities to deliver these interventions should be assessed alongside the accessibility of interventions for patients (Wang *et al.* 2019).

A key factor which may impact staff members' abilities to implement non-pharmacological interventions is their own emotional wellbeing. Burnout is recognised as a psychological experience related to emotional stress and strain at work (Maslach & Jackson 1981) and can be characterised in three dimensions. 'Emotional exhaustion' describes symptoms of fatigue, depletion and reduced capacity to respond to the needs of others. Symptoms of indifference and cynicism towards work and others are characterised as 'depersonalisation', while 'reduced personal achievement', or 'inefficacy' captures a decreased sense of achievement, productivity, morale and ability to cope (Maslach *et al.* 2001; Maslach & Leiter 2016) A number of models have been suggested to explain the development of burnout, including sequential models suggesting that one dimension leads to another. Alternatively, developmental models consider that burnout may result from an imbalance between demands of the job and the individual's resources to meet these demands (Maslach & Leiter 2016). These models take account of the role of organisational factors, such as work demands, renumeration/rewards, values and availability of resources in influencing the development of burnout.

Healthcare workers are among those most at risk of burnout (Health and Safety Executive 2017; Maslach 2003) while nursing staff (often the staff group implementing dementia interventions in an in-patient setting) have been identified to exhibit even greater burnout than other healthcare professionals (Chou *et al.* 2014). Staff burnout has been reported to be associated with poorer patient care, including reduced willingness to help; low optimism; negative emotional responses; poorer relationships with patients and carers; increased staff sickness rates and high staff turnover (Mackenzie & Peragine 2003; Todd & Watts 2005).

Estimates of burnout prevalence among dementia care staff vary widely in the literature, from 29.5% (Costello *et al.* 2019) to 68.6% (Duffy *et al.* 2009) in at least one subscale. Two important factors which can mediate healthcare staff's risk of burnout, are sense of self-efficacy and reciprocity in staff-patient relationships (Alidosti et al., 2016; Duffy et al., 2009; Mackenzie & Peragine, 2003).

Self-efficacy or sense of self competence is the belief in oneself to accomplish specific goals (Bandura 1978). In dementia care, high staff self-efficacy leads to a more positive experience of providing care for patients with dementia, better mood and better coping, as well as better outcomes for those receiving care (Duffy *et al.* 2009; Schepers *et al.* 2012; Semiatin & O'Connor 2012). Interventions to improve self-efficacy among staff working in dementia care have been shown to facilitate short-term improvements in burnout; however, there is less evidence these are maintained in the longer term (Awa *et al.* 2010; Mackenzie & Peragine 2003).

A lack of reciprocity in the relationship between staff and the people whom they care for can be found in situations where the care professional feels they invest more in energy in the relationship than is invested by the recipient of care (Duffy *et al.* 2009). This is relevant in dementia care settings, as the instance of poorer cognitive abilities, stress and distress and decreased social ability may be detrimental to staff relationships with those they care for. There is a societal perception that people with dementia, particularly those with advanced dementia, lack reciprocity (Gove et al., 2017), suggesting this may be a particular risk factor for burnout in dementia care staff, however, evidence of this to date is mixed (Duffy *et al.* 2009; Rose *et al.* 2010).

Interventions to reduce burnout among dementia care staff often focus on the staff themselves. A systematic review of staff training programs found that training in topics such as 'managing challenging behaviours' and 'person-centred care' increased staff self-efficacy and reduced burnout, although the studies in the review were of mixed quality(Spector *et al.* 2016). Increasingly, there has also been interest in examining whether interventions directed towards patients have benefits for staff wellbeing. Person-centred care interventions have demonstrated benefits for staff as well as patients. Five of seven papers reviewed by Barbosa *et al.* (2015) reported reduction in care worker burnout following person-centred care interventions. The papers in this review were also, however, impacted by a range of methodological weaknesses, and as such, the link between person-centred interventions and

benefits for staff wellbeing are tentative, with the underlying mechanisms poorly understood. Van Weert *et al.* (2005) demonstrated significant effects in measures of staff sense of self-competence, emotional exhaustion and job satisfaction following the introduction of Snoezelen therapy in nursing homes. The authors suggest that providing staff with activities which they can use to make a difference in the lives of people with dementia promotes an increase in staff sense of efficacy and autonomy.

Technology-based non-pharmacological interventions in dementia care

Use of technology in dementia care settings, provides meaningful activity while placing little additional pressure on staff (Dove & Astell 2017). Wada *et al.* (2004) found staff experiencing sub-clinical levels of burnout showed small improvements in burnout scores after the introduction of the PARO robot to the care setting. While this study may suggest a potential connection between a patient-orientated technology intervention and staff outcomes, the sample size was very small (n=6), the time scale for the study was relatively short (6 weeks) and only descriptive statistics were reported. Significantly more rigorous investigation is required before conclusions about the potential for robots, or other technology interventions to positively impact staff can be determined.

Other studies have reported improved rapport between staff and patients using tablet devices in dementia care settings. Swan *et al.* (2018) gathered data on staff experiences through qualitative interviews, and found staff reported improved relationships, better understanding of those in their care and some improvements in ‘ challenging behaviour’, however, this study does not specifically address reciprocity in the relationships nor the overall impact on staff wellbeing. Upton *et al.* (2011) also reported improved staff-patient relationships following the introduction of tablet devices, but again, the impact of these improved relationships on staff burnout outcomes was not considered. There is preliminary evidence to suggest that there are some benefits of technology us on staff-patient relationships, but whether this leads to increased reciprocity, with associated benefits for staff burnout, is still poorly understood. Technology-based activities are reported to be relatively widely used in community settings, there is less evidence of the use of appropriate activities using technology for those with advanced dementia (Anderiesen 2017), and of their use in hospital settings.

The Tovertafel (https://tovertafel.com), meaning Magic Table in Dutch, was designed with accessibility in mind (Anderiesen 2017). The ceiling-mounted device projects images on to a table below and utilises infrared technology to detect the position of an individual's hands in relation to the projected images. Participants can engage with the objects projected on to the

table, allowing them to play the Tovertafel's many games designed specifically for people with dementia. While there is some preliminary evidence of benefit to patients (Bruil *et al.* 2018), nothing is known of the Tovertafel's impact on staff in dementia care settings. This exploratory study aims to consider the impact on staff of the introduction of a Tovertafel in an acute dementia care in-patient ward. To provide a broad picture of the impact on staff of introducing the Tovertafel, a mixed method design is used to capture both qualitative and quantitative data. Qualitative data will provide a report on staff perceptions of the Tovertafel, while a multiple-baseline single-case methodology is used to quantitively understand staff experiences of burnout, sense of competence and reciprocity at both the individual and group level.

Method

Design and Ethics

A mixed-method multiple-baseline single-case study was conducted. The multiple-baseline single-case study is made up of three phases. Phase A consists of three staggered baselines, as per the guidelines set out by Horner *et al.* (2005), which suggest the need for three or more baselines across three or more participants. While Horner's guidelines suggest that baselines containing at least 5 data points are ideal, shorter baselines can still be appropriate.In this study, baselines consisting of three, four or five consecutive shifts worked by staff were chosen as an appropriate balance between the need to establish a degree of stability in the baseline and the concern about overburdening staff with onerous data collection. Due to shift patterns, these baselines may take place over two weeks. Phase B is the intervention phase, where the Tovertafel is introduced to the ward (12 weeks), and Phase C is a follow-up observation phase (three weeks) to determine if any changes observed in Phase B are maintained. A representation of the study design can be found in Figure 1.For the multiple-baseline arm of the study, participants completed individual items from the standardised outcome measures which were selected by them, in consultation with the researcher, to be meaningful to them and their work as a group and as individuals. Alongside this, a shift by shift measure of satisfaction at work was completed.

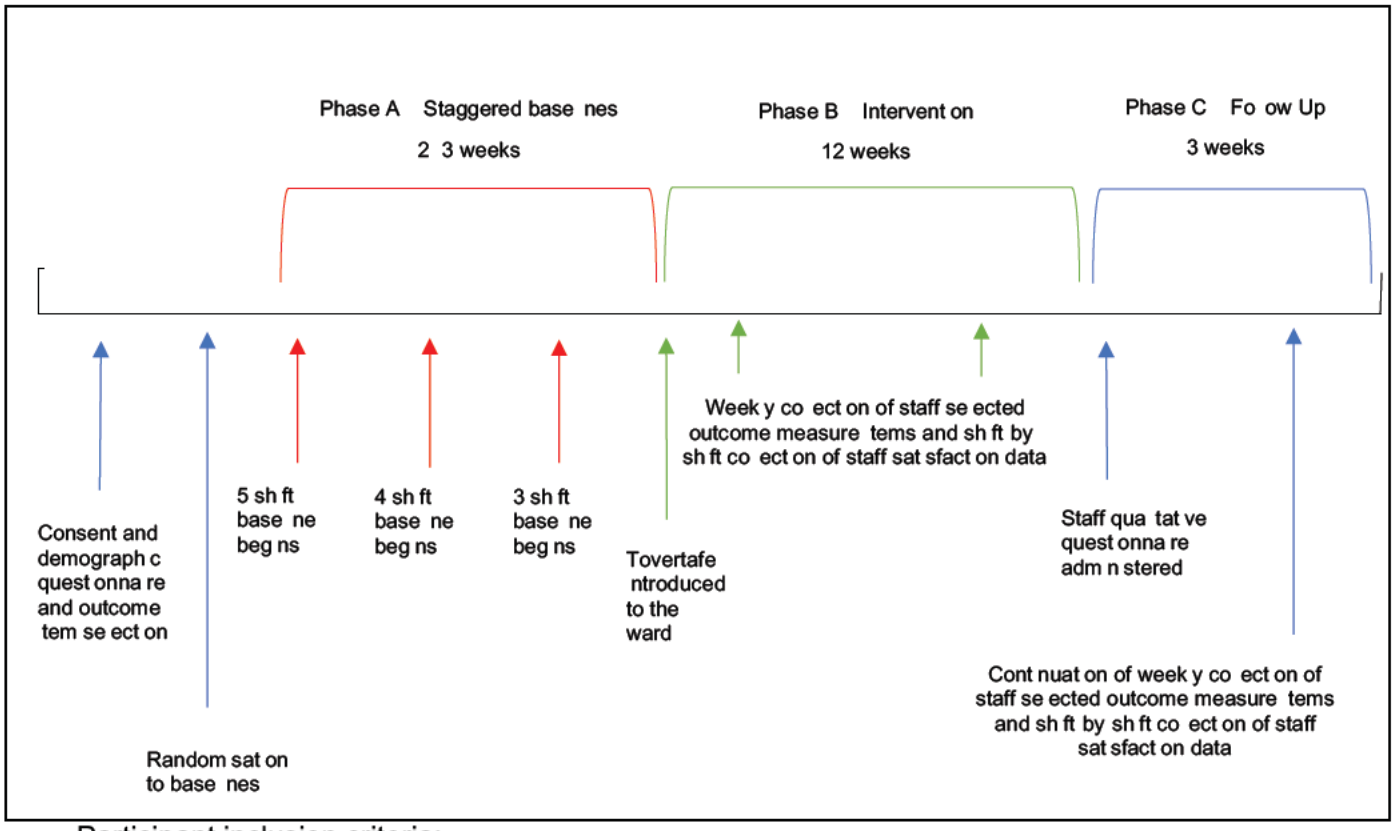
The qualitative aspect of the study utilised a short questionnaire completed by staff at the end of Phase B about their experiences of working on the ward while the Tovertafel was being used.

The study was granted ethical approval by the University of Edinburgh Department of Clinical and Health Psychology Ethics Research Panel, reference number: CLIN649 (See Appendices I & J).

Setting, Participants and Randomisation Procedure

The setting for this study was the NHS psychiatric hospital in Dumfries and Galloway, a rural health board in south-west Scotland. The acute dementia care ward was chosen from the two wards which care for dementia patients as it has a population exclusively of people living with dementia and has a staff team which is relatively consistent and stable. The chosen ward is a 16-bed acute admission ward for patients diagnosed with dementia; therefore, the patient population comprises individuals who are often acutely unwell, and frequently in the advanced stages of dementia.

Figure 1 – Diagram of study design



Participant inclusion criteria:

1. A registered nurse (any grade) or Health Care Assistant (HCA) (any grade) who routinely worked exclusively on the ward
2. Able to read and speak English fluently
3. Available to commit to the project for 24 weeks
4. Aged over 16 years of age.

Participant exclusion criteria:

1. Temporary staff expected to be on the ward for less than the duration of the study
2. Senior nurse managers who do not routinely work 'hands-on' on the ward
3. Nursing students on placement within the ward
4. Staff who do not routinely work on the ward (i.e. temporary cover from other wards)
5. Members of staff who visit the ward but do not solely work there (e.g. medical staff/psychologists/ allied health professionals).

A random number generator in the Statistical Package for the Social Science (SPSS, version 24) was used to allocate participants to one of the three baselines (three, four or five shifts). Baseline start times were staggered, so all participants started the intervention period at the same time.

Intervention

The Tovertafel device was placed on the ward at the beginning of Phase B. Staff could initiate its use whenever they felt this was appropriate, day or night. Staff encouraged patients to make use of the Tovertafel for as long as they wished, as appropriate given other ward activities.

Outcome measures

Use of the Tovertafel

Staff maintained a record of the use of the Tovertafel on the ward during the study period, recording the duration of use and the number of staff and patients involved in the session.

Staff demographic information questionnaire

Staff were asked to provide demographic information in the form of a short questionnaire, adapted from (Duffy *et al.* 2009) (See Appendix F). Unfortunately, staff absence data could not be collated due to operational restrictions as a result of the COVID19 pandemic.

Abbreviated Maslach Burnout Inventory (aMBI)

The abbreviated Maslach Burnout Inventory (aMBI) (McManus *et al.* 2002) comprises three subscales: emotional exhaustion (EE), depersonalisation (DP), and personal achievement (PA). Higher scores on emotional exhaustion and depersonalisation and lower scores of personal achievements result in higher overall burnout scores. The scale items are measured on a seven-point scale, indicating the frequency with which each burnout item is experienced.

Sense of Competence in Dementia Care Staff (SCIDS) Scale

The Sense of Competence in Dementia Care Staff (SCIDS) Scale (Schepers *et al.* 2012), provides a measure of staff's feelings of competence in their role. Respondents indicate how

well they feel they can accomplish different aspects of dementia care across 17 items, on a four-point scale.

Jeffcott Reciprocity Questionnaire

The Jeffcott Reciprocity Questionnaire *(*Jeffcott, 2002), adapted from Van Horn *et al.'s* (2001) measures of reciprocity in work relationships, was utilised in children's healthcare settings but has subsequently been adapted by Duffy et al. (2009) for use in populations of staff providing care in dementia. Only the staff-patient reciprocity subscale, which consists of six items, measured across a six-point scale, was utilised in this study to provide a measure of the perceived reciprocity in the relationships between staff and their patients.

Shift by shift measure of staff satisfaction

In order to provide a shift by shift measure of staff satisfaction unobtrusively, a token collection system was placed on the ward. Staff were allocated tokens marked with their participant ID number and were asked to answer the question: "Thinking about your whole shift, how was your day at work?" at the end of each shift by 'voting' with their tokens. Staff answered on a five-point scale by selecting a token of the colour which corresponded to their answer: "Great"; "Good"; "OK" "Not good"; or "Awful" and placing in a collection box (See Appendix G).

Qualitative Questionnaire

The qualitative questionnaire posed six questions regarding staff experiences of their work over the course of the study (See Appendix H).

Individual outcome items

Participants completed each of the standardised outcome measures (aMBI, SCIDS and Jeffcott Reciprocity Questionnaire) before Phase A began. A total of five individual outcome items from each standardised outcome measures were selected as being relevant to the staff group and the study question. The items 'I feel emotionally drained from my work'; 'How well do you feel you can offer stimulation (for the mind, the senses and the body) to a person with dementia in your daily work?'; and 'How much appreciation do the older adults in your care have for you?' were chosen as relevant to the group of participants as a whole. In line with this person-centred research approach, participants then met individually with the lead researcher to select two further items from any of the standardised measures which they felt were important to them and their work and which could be improved. The individual outcome items are shown in Table 1.

Statistical analysis

Demographic and Tovertafel use Data

Descriptive statistics on the demographics of participants will be reported, including means and ranges. Descriptive statistics will also be reported for the data on the use of the Tovertafel.

Percentage All Non-Overlapping Data

Scores from the individual outcome items and the shift by shift measure of staff satisfaction were graphed to allow for visual analysis of variation between phases. A percentage of all non-overlapping data (PAND) analysis was then conducted. A brief description of the method follows, with a full description of each step detailed in Guzmán *et al.* (2016) (see Appendix K).

1. From the graph and a spreadsheet of the data, sorted by the expected trend of the data, PAND is calculated. PAND is defined as "the percentage of data remaining after removing the fewest data points that would eliminate all overlap" (Parker *et al.* 2011, p.340) or as the “minimum number (of data points) that would have to be swapped across phases for complete score separation” (Parker *et al.* 2007 p.197). Essentially this means that PAND is equal to the percentage of data which causes an overlap in the data between Phases A and B. When this data is hypothetically removed or switched to the other phase, there would be complete separation between the data, with all the data in Phase A falling either above or below the data in Phase B. The cut-off point is a line which could be drawn across the graphs of both phases to indicate where this separation occurs. Expected trend can be defined as the data pattern which would be observed if the outcome measure reported improvement in burnout factors. For example, in the item “I feel emotionally drained from my work”, decreasing scores indicate a lower frequency of occurrence and improvement in wellbeing. Scores for this item would therefore be sorted in a descending trend to identify the cut-off point. In keeping with the single case methodology, this cut-off point is calculated individually, for each participant, as baseline levels for each item varied by participant. With the level of chance of PAND being 50%, it is then re-scaled to a 0-100 scale to allow easier comparison with other standardised indicators, using the formulae ((non-overlap/0.5) – 1) (Parker *et al.* 2011).

2. The next step is to calculate Phi to provide a measure of effect size. Parker *et al.* (2011, 2007) recommends calculating a “robust phi” based upon a balanced 2x2 contingency table. This table is used to compute Phi and its confidence intervals. An online Phi

calculator (Pezzullo, 2010 http://statpages.org/ctab2x2.html) was used in this case. The table is constructed by using the number of data points found above and below the cut-off point in both Phases A and B.

3. Effect sizes are then interpreted based on the criteria established by Parker *et al.* (2011) for small scale research studies (see Appendix L). As highlighted by Guzmán *et al.* (2016), these criteria are only based on the studies included in Parker et al.'s analysis and are likely to favour larger effects; however, Parker et al.'s criteria still represent a better interpretation of effect size in single-case research than Cohen's conventions.

4. A summary of the magnitude of change of the three individual outcome items that were used across all participants and the shift by shift satisfaction measure is achieved by a meta-analysis which aggregates the effect size across all participants. This is carried out using the WINPEPI programme COMPARE2.EXE (Abramson 2011).

In order to be included in the analysis, sufficient data was required from each participant. Data sets insufficient for analysis were those without complete Phase A baselines, or where the number of data points collected in Phase B fell below the number of data points collected in Phase A. A lack of follow up data did not constitute a reason for exclusion from the analysis. Fisher's exact tests (due to the small sample sizes) and Mann-Whitney tests will be used to determine if a significant difference exists between the participants included and excluded from the analysis.

Qualitative Data

Given little is known of staff experience of this type of technology-based non-pharmacological intervention, a thematic analysis was applied to analyse the data transcribed from the participant questionnaires, in part due to the flexible nature lending itself well to an exploratory study. Data was imported in to Nvivo12 quantitative analysis software to allow coding and themes to be tracked across participants. An inductive thematic analysis allows for a bottom-up, exploratory analysis of the data without preconceived theoretical framework (Braun & Clarke 2006), and as little is already known about how staff would react to the introduction of an intervention such as the Tovertafel, this was felt to be the appropriate approach in this case. A semantic approach was also taken in the analysis, with themes developed from the

explicit data provide by participants without attempting to theorise about latent beliefs, assumptions or contexts, as the evidence on which to base these is too limited to theorise at this level given the current stage of the research.

Table 1 – Individual Outcome items by participant

Participant	Burnout	Sense of Competence	Reciprocity
A	I feel emotionally drained from my work Working with people all day is a strain for me	How well do you feel you can offer stimulation (for the mind, the senses and the body) to a person with dementia in your daily work?	How much appreciation do the older adults in your care have for you? How many of your skills do you invest in your relationships with the older adults in your care?
B	I feel emotionally drained from my work Working with people all day is a strain for me	How well do you feel you can offer stimulation (for the mind, the senses and the body) to a person with dementia in your daily work? How well do you feel you can understand the feelings of a person with dementia?	How much appreciation do the older adults in your care have for you?
C	I feel emotionally drained from my work Working with people all day is a strain for me	How well do you feel you can offer stimulation (for the mind, the senses and the body) to a person with dementia in your daily work? How well do you feel you can keep yourself motivated during a working day?	How much appreciation do the older adults in your care have for you?
D	I feel emotionally drained from my work I feel I'm positively influencing other people's lives through my work	How well do you feel you can offer stimulation (for the mind, the senses and the body) to a person with dementia in your daily work? How well do you feel you can plan an active role in your staff team?	How much appreciation do the older adults in your care have for you?

E	I feel emotionally drained from my work I feel fatigued when I get up in the morning and have to face another day on the job	How well do you feel you can offer stimulation (for the mind, the senses and the body) to a person with dementia in your daily work? How well do you feel you can deal with behaviour that challenges in a person with dementia?	How much appreciation do the older adults in your care have for you?
F	I feel emotionally drained from my work	How well do you feel you can offer stimulation (for the mind, the senses and the body) to a person with dementia in your daily work? How well do you feel you can engage a person with dementia in creative activities during your normal working day?	How much appreciation do the older adults in your care have for you? How much effort to make positive change do you see from the older adults in your care?
G	I feel emotionally drained from my work	How well do you feel you can offer stimulation (for the mind, the senses and the body) to a person with dementia in your daily work? How well do you feel you can engage a person with dementia in a conversation?	How much appreciation do the older adults in your care have for you? How much effort to make positive change do you see from the older adults in your care?
H	I feel emotionally drained from my work	How well do you feel you can offer stimulation (for the mind, the senses and the body) to a person with dementia in your daily work How well do you feel you can engage a person with dementia in a conversation? How well do you feel you can engage a person with dementia in creative activities during your normal working day?	How much appreciation do the older adults in your care have for you?

I	I feel emotionally drained from my work I feel fatigued when I get up in the morning and have to face another day on the job	How well do you feel you can offer stimulation (for the mind, the senses and the body) to a person with dementia in your daily work? How well do you feel you can engage a person with dementia in creative activities during your normal working day?	How much appreciation do the older adults in your care have for you?
J	I feel emotionally drained from my work	How well do you feel you can offer stimulation (for the mind, the senses and the body) to a person with dementia in your daily work? How well do you feel you can deal with behaviour that challenges in a person with dementia? How well do you feel you can engage a person with dementia in creative activities during your normal working day?	How much appreciation do the older adults in your care have for you?
K	I feel emotionally drained from my work	How well do you feel you can offer stimulation (for the mind, the senses and the body) to a person with dementia in your daily work? How well do you feel you can keep yourself motivated during a working day? How well do you feel you can engage a person with dementia in creative activities during your normal working day?	How much appreciation do the older adults in your care have for you?
L	I feel emotionally drained from my work	How well do you feel you can offer stimulation (for the mind, the senses and the body) to a person with dementia in your daily work? How well do you feel you can engage a person with dementia in creative activities during your normal working day?	How much appreciation do the older adults in your care have for you? How much do you invest in the relationship with the older adults in your care?

M	I feel emotionally drained from my work	How well do you feel you can offer stimulation (for the mind, the senses and the body) to a person with dementia in your daily work? How well do you feel you can keep a positive attitude towards relatives of a person with dementia? How well do you feel you can keep yourself motivated during a working day?	How much appreciation do the older adults in your care have for you?
N	I feel emotionally drained from my work I feel I'm positively influencing other people's lives through my work	How well do you feel you can offer stimulation (for the mind, the senses and the body) to a person with dementia in your daily work? How well do you feel you can keep yourself motivated during a working day?	How much appreciation do the older adults in your care have for you?
O	I feel emotionally drained from my work I feel exhilarated after working closely with my patients	How well do you feel you can offer stimulation (for the mind, the senses and the body) to a person with dementia in your daily work How well do you feel you can understand the way a person with dementia interacts with the people and things around them ?	How much appreciation do the older adults in your care have for you?

Results

Fifteen staff members were recruited into the study, with none meeting exclusion criteria. Of these fifteen, nine participants (A,B,C,F,H,I,K,M&O) returned sufficient data to carry out PAND analyses on their individual target outcomes. Ten participants (A,B,E,F,H,I,J,K,M&O) returned sufficient data to carry out PAND analyses on their shift by shift satisfaction outcome. Eight participants (A,B,C,E,H,K,M&O) returned qualitative data. In total, 11 of the 15 recruited participants returned sufficient data to be included in at least one aspect of the analysis. A summary of the demographic characteristics of participants included and excluded can be found in Table 2, alongside the results of the tests of difference between the included and excluded groups. There were no significant differences between the groups on demographic characteristics.

Tovertafel use ranged from 20 to 90 minutes at a time, with a mean of 51 minutes. The number of patient participants using the Tovertafel at one time ranged from 1 to 4, with an average of 2.6 and the number of staff participants ranged from 1 to 3, with an average of 1.6.

Percentage All Non-Overlapping Data (PAND) Analysis

The results of the PAND analysis of individual outcome items are summarised in Table 3. Graphical representations of participant's results of the 'Feeling emotionally drained from work' item are presented in Figure 2. Graphs of Phases A, B and C are presented for each participant included in the analysis. Trend lines are presented on each applicable graph. The number of data points in the baseline graphs varies depending on the participants' random allocation to a three, four or five shift baseline. Gaps in the data points indicate missing data. For example, Participant A's graphs show a stable five-day baseline in Phase A, with a downward trend in Phase B, where there are three missing data points over the 12-week period. The graph representing Phase C shows a stable trend with one missing data point. Only one data point (week 5 of Phase B) of the 15 data points in Phases A and B is 'overlapping' (i.e. would be required to be removed / swapped across phases to allow for complete separation of the data between Phases A and B). The non-overlapping data is therefore 14/15 data points and the Percentage of Non-Overlapping (PAND) data is 93%, recalculated using ((non-overlap/0.5) – 1) (Parker *et al.* 2011). The Phi effect size is calculated to 0.850 (95% C.I. 0.179-1.00), suggesting a large effect size. The stable trend in Phase C suggests that this is maintained in the follow up phase.

Graphs depicting the results of the "How well do you feel you can offer stimulation (for the mind, the senses and the body) to a person with dementia in your daily work?" item and the "How much appreciation do the older adults in your care have for you?" item can be found in Appendices M & N.

Ten of the 45 individual outcomes items show a large PAND effect of the introduction of the Tovertafel; 19 show medium effects; two show small effects, and 11 show no effects. Three individual outcome items, across two participants, show an adverse PAND effect after the introduction of the Tovertafel. Of the 31 individual outcome items which show improvement, 27 maintained or further improved during Phase C follow up.

The results of the analysis of the shift by shift measure of satisfaction at work are summarised in Table 4, with a graphical representation displayed in Figure 3. Six participants showed small to medium positive effects following the introduction of the Tovertafel, one showed no effect, and three participants demonstrated small to medium adverse effects.

Table 2 - Characteristics of Participants and results of tests of difference between included and excluded groups

Demographic	Participants included in the analysis (n=11)	Participants excluded from the analysis (n=4)	p- value of tests of difference between groups
Age[1]	x=41.7 years (S.D.=14.5) Range: 22-62	x=30.0 years (S.D.=4.3) Range: 26-36	0.280
Gender[2]	Female: 90.9% Male: 9.1%	Female: 100.0% Male: 0%	0.733
Job roles [2]	Staff nurse=36.4% Charge nurse= 9.1% Health care support worker (HCA) = 18.2% Senior health care support worker = 36.4%	Staff nurse=50.0% Health care support worker = 50.0%	0.543
Length of time working in the NHS[1]	x=14.8 years (S.D.=12.9) range: 1.5 months - 41 years	x=3.4 years (S.D.=2.06) range: 1- 6 years	0.056
Length of time working this particular ward[1]	x=7.1 years (S.D.= 6.8) range: 1 month - 20 years	x=1.4 years (S.D.= 1.5) range: 1 month – 3.5 years	0.138
Contracted hours per week[1]	x=33.2 hours (S.D.=5.2) range: 20 – 37.5 hours	x=33.8 hours (S.D.=4.3) range: 30 – 37.5 hours	1.00
Hours actually worked in the previous week[1]	x=34.0 hours (S.D.=5.9) range: 20-39.5 hours	x=28.9 hours (S.D.=19.3) range: 0-40 hours	0.489
If extra hours were worked, was this your choice?[2]	Yes=18.2%. No=0% N/A=81.8%	Yes=50.0%. No=25.0% N/A=25.0%	0.077
How challenging do you perceive the behaviour of the patients you work with to be? [2]	Slightly=27.3% Moderately =45.5% Very=27.3% Extremely=0%	Slightly=0% Moderately =50.0% Very=25.0% Extremely=25.0%	0.451
Relationship status[2]	Single= 36.4% Living with partner= 63.6%	Single= 25.0% Living with partner= 75.0%	0.593
Have dependent children[2]	Yes = 9.1%. No=90.9%	Yes = 50.0%. No=50.0%	0.154
Have dependant others[2]	No = 100%	No=100%	-

[1] Denotes Mann-Wh tney test [2] Denotes F sher s exact test

Table 3 - PAND Results for individual outcome items

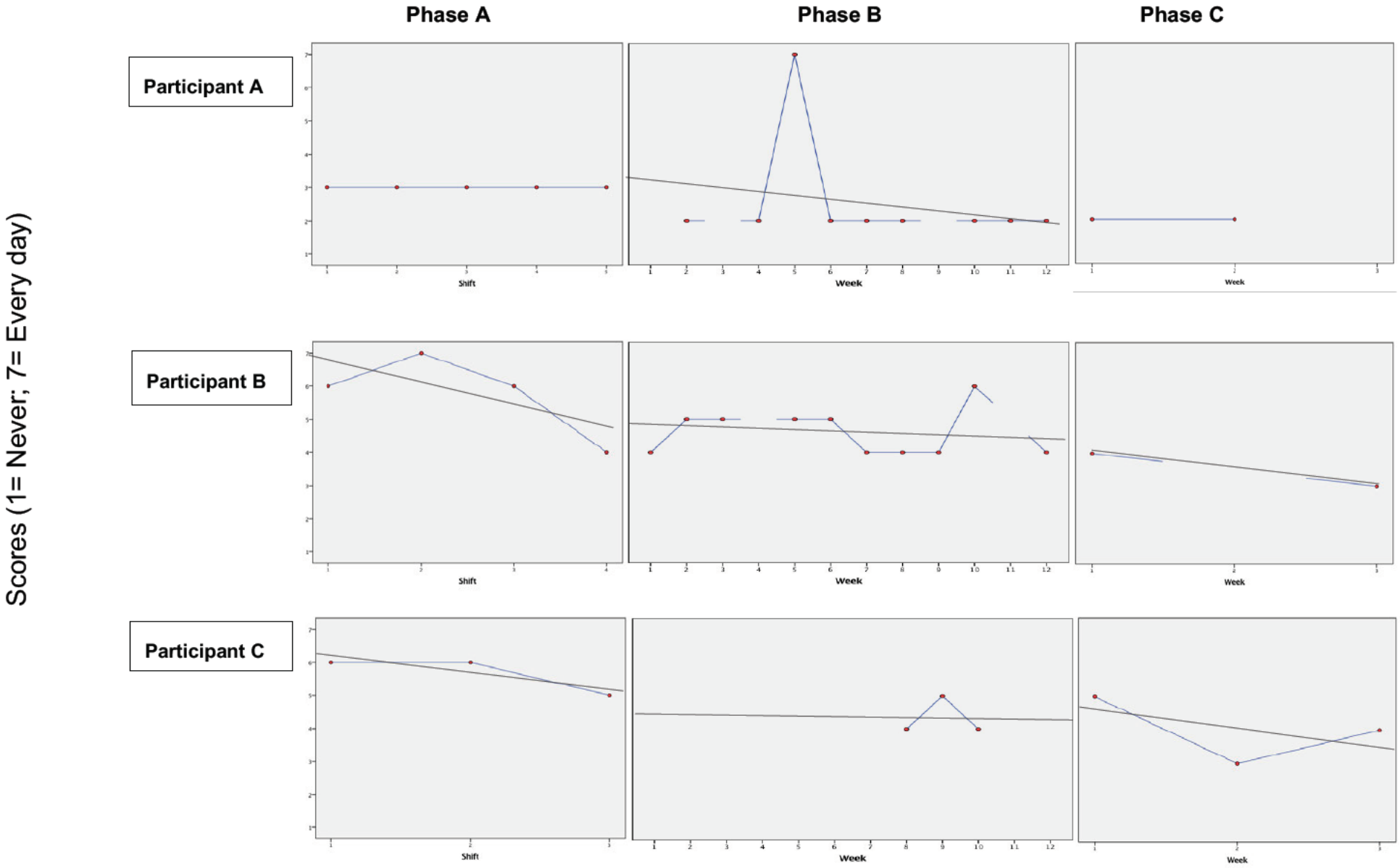
Participant	Worsening	No effect	Small Effect	Medium Effect	Large effect
A		Working with people all day is a strain for me Offering stimulation to a person with dementia Investing skills in your relationships with the older adults in your care			Feeling emotionally drained from my work* Appreciation that adults in your care have for you*
B	Understand the feelings of a person with dementia (small effect)		Offering stimulation to a person with dementia	Feeling emotionally drained from my work Working with people all day is a strain for me	Appreciation that adults in your care have for you*
C			Working with people all day is a strain for me	Feeling emotionally drained from my work Offering stimulation to a person with dementia Keeping yourself motivated during a working day Appreciation that adults in your care have for you	
F		Appreciation that adults in your care have for you		Feeling emotionally drained from my work Offering stimulation to a person with dementia Effort to make positive change from the older adults in your care	Engaging a person with dementia in creative activities *

Participant	Worsening	No effect	Small Effect	Medium Effect	Large effect
H				Feeling emotionally drained from my work Engaging a person with dementia in a conversation Engaging a person with dementia in creative activities Appreciation that adults in your care have for you	Offering stimulation to a person with dementia
I		Appreciation that adults in your care have for you		Feeling emotionally drained from my work	I feel fatigued having to face another day on the job Offering stimulation to a person with dementia Engaging a person with dementia in creative activities
K				Offering stimulation to a person with dementia* Keeping yourself motivated during a working day Engaging a person with dementia in creative activities* Appreciation that adults in your care have for you	Feeling emotionally drained from my work*(Phi medium effect)

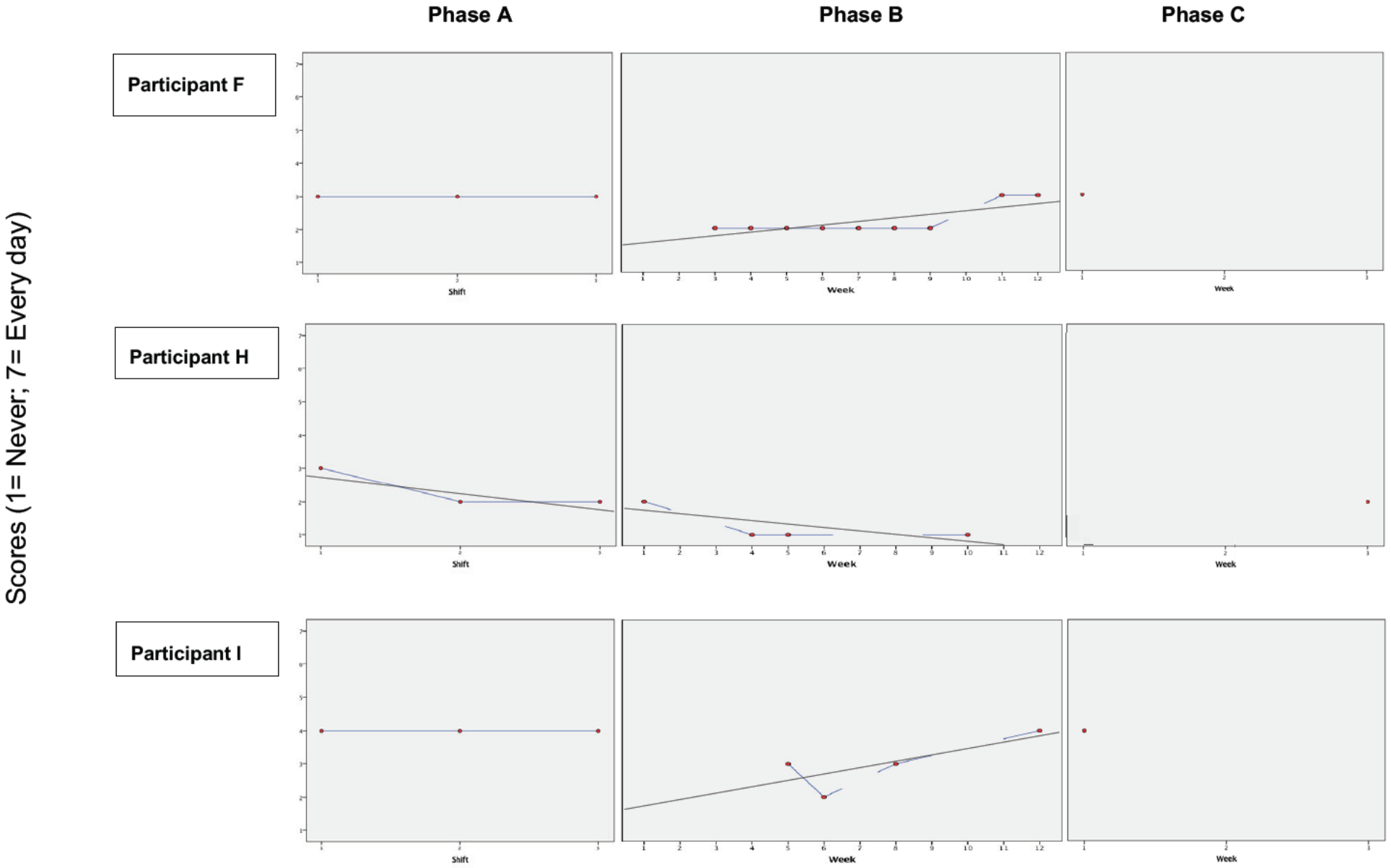
Participant	Worsening	No effect	Small Effect	Medium Effect	Large effect
M		Feeling emotionally drained from my work Offering stimulation to a person with dementia Keeping a positive attitude towards relatives of a person with dementia Keeping yourself motivated during a working day Appreciation that adults in your care have for you			
O	Feeling exhilarated after working closely with my patients (large effect) * Offering stimulation to a person with dementia (small effect)	Appreciation that adults in your care have for you		Understanding the way a person with dementia interacts with the people and things around them	Feeling emotionally drained from my work*

*Denotes significant phi result

Figure 2 – Graphs of responses to "I feel emotionally drained from my work" item by participant



Graphs show the participant responses to the item: "I feel emotionally drained from my work" at Baseline (Phase A), Intervention (Phase B) and Follow up (Phase C). Frequency of measurement in Phase A was on a shift by shift basis, and weekly in Phases B & C. Baselines were randomly allocated at 3,4, or 5 consecutive shifts. Lower scores indicate less emotional exhaustion.



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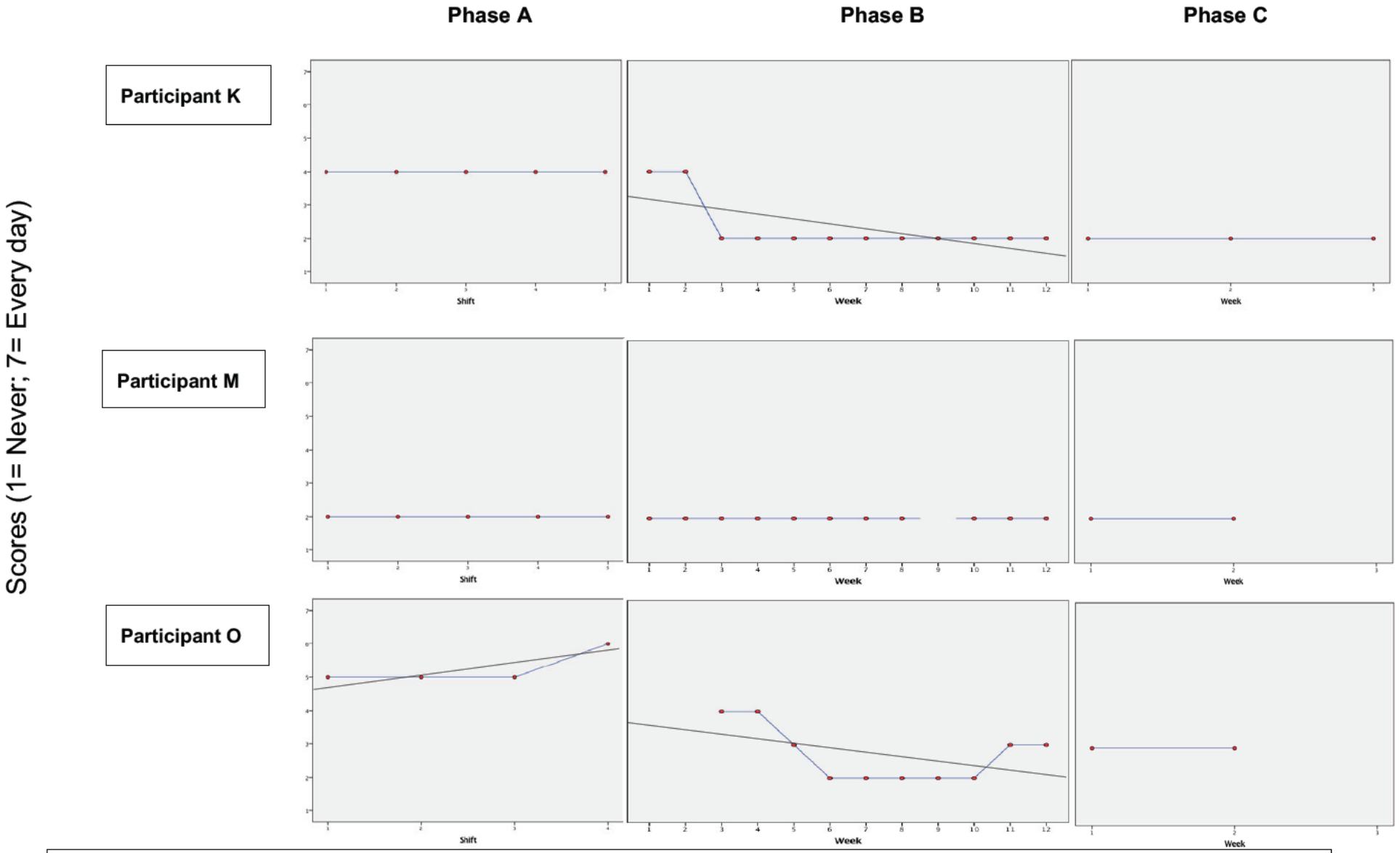


Graphs show the participant responses to the item: "I feel emotionally drained from my work" at Baseline (Phase A), Intervention (Phase B) and Follow up (Phase C). Frequency of measurement in Phase A was on a shift by shift basis, and weekly in Phases B & C. Baselines were randomly allocated at 3,4, or 5 consecutive shifts. Lower scores indicate less emotional exhaustion.

Meta-Analysis

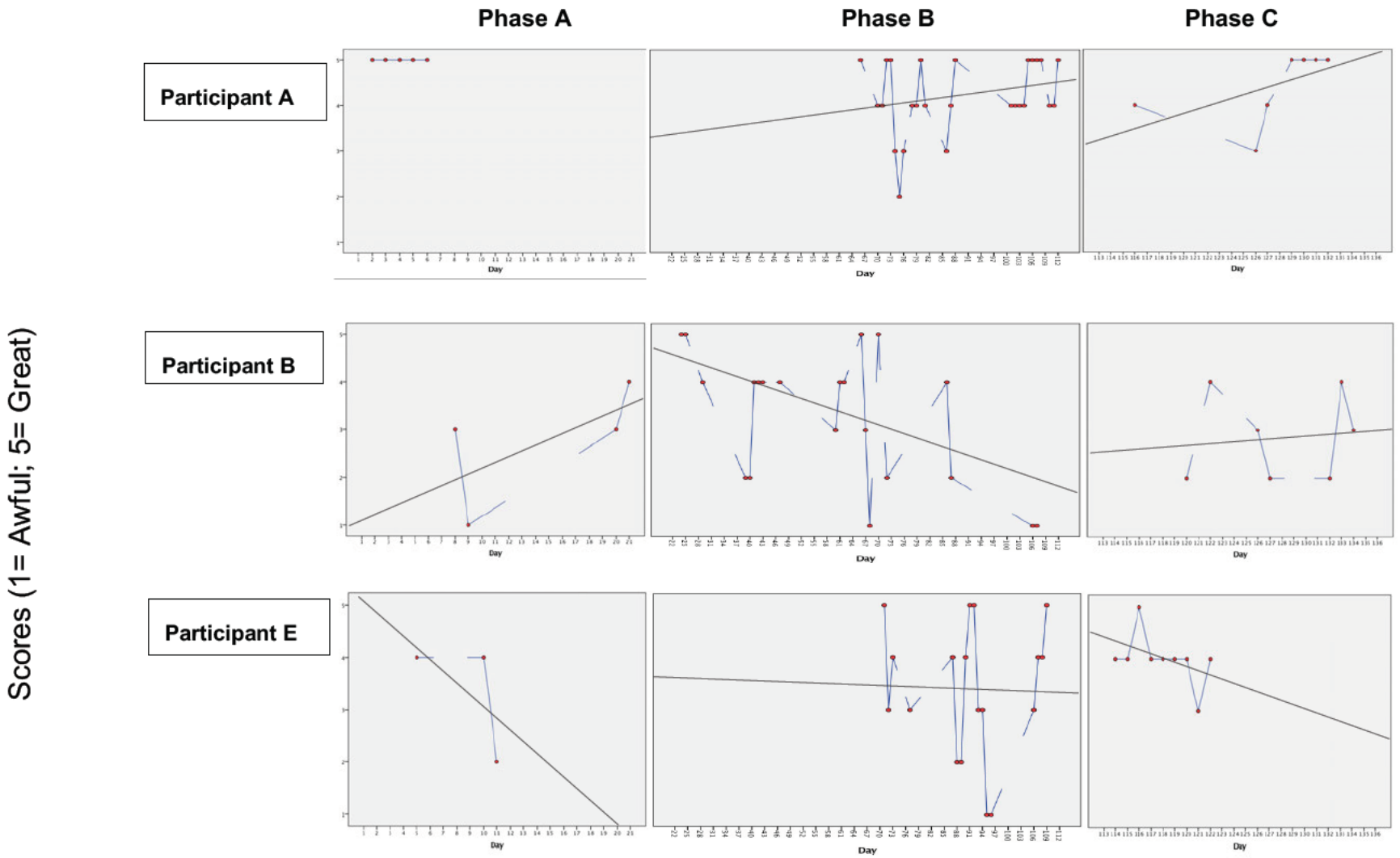
Phi results from the 'Feeling emotionally drained from work', 'Offering stimulation to people with dementia' and 'Feeling appreciation from the older adults in their care' were aggregated within each item to produce an average across participants. Results suggested an average Phi of 0.69 (95% C.I.= 0.51 - 0.87) for 'Feeling emotionally drained from work', suggesting an overall medium effect, based on Parker *et al.'s* (2011) effect size conventions for small scale research studies. The average Phi for 'Offering stimulation to people with dementia' = 0.39 (95% C.I.=0.03 -0.75), suggesting a small-medium effect, while an average Phi of 0.36 (95% C.I.= 0.01- 0.71) for 'Feeling appreciation from the older adults in your care' suggests a small effect. The meta-analysis for the shift-by-shift satisfaction at work measure produced a Phi of 0.01 (95% C.I.= -0.18 -0.19), suggesting no effect.

Table 4 – PAND Results Shift by shift satisfaction measure effect

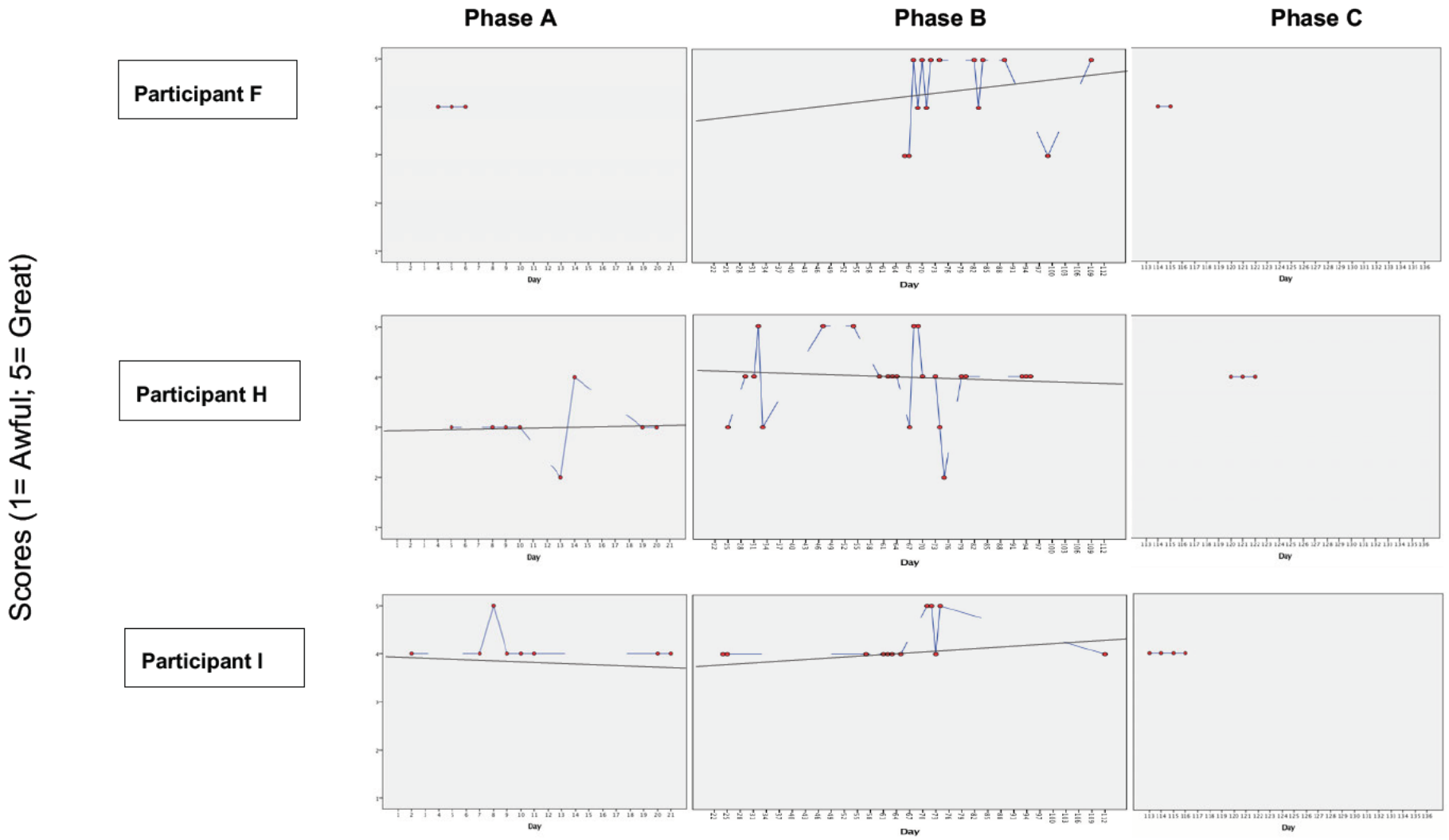
Participant	PAND result
A	Small negative effect
B	Medium positive effect
E	Medium negative effect
F	Small positive effect
H	Medium positive effect*
I	No effect
J	Medium positive effect
K	Medium positive effect
M	Medium positive effect
O	Medium negative effect*(phi suggests small negative effect)

*Denotes significant phi result

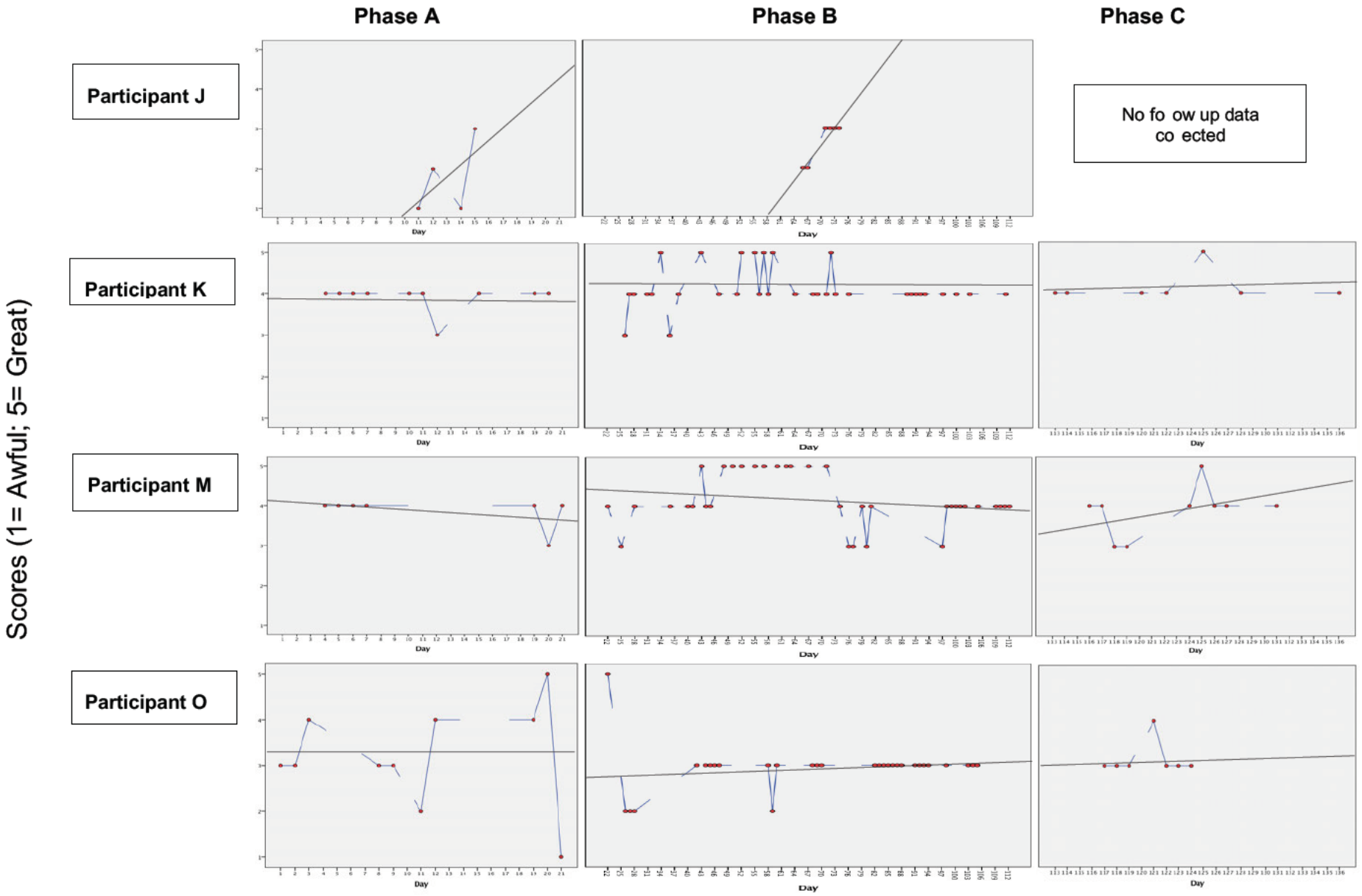
Figure 3– Graphs of responses to shift by shift satisfaction measure by participant



Graphs show the participant responses to the shift-by shift satisfaction item: "How was your day at work?" at Baseline (Phase A), Intervention (Phase B) and Follow up (Phase C). Frequency of measurement was on a shift by shift basis,. Baselines were randomly allocated at 3,4, or 5 consecutive shifts, however, some participants provided additional data in this phase, which has been included in the analysis. Higher scores indicate greater satisfaction.



Graphs show the participant responses to the shift-by shift satisfaction item: "How was your day at work?" at Baseline (Phase A), Intervention (Phase B) and Follow up (Phase C). Frequency of measurement was on a shift by shift basis. Baselines were randomly allocated at 3,4, or 5 consecutive shifts, however, some participants provided additional data in this phase, which has been included in the analysis. Higher scores indicate greater satisfaction.



Graphs show the participant responses to the shift-by shift satisfaction item: "How was your day at work?" at Baseline (Phase A), Intervention (Phase B) and Follow up (Phase C). Frequency of measurement was on a shift by shift basis. Baselines were randomly allocated at 3,4, or 5 consecutive shifts, however, some participants provided additional data in this phase, which has been included in the analysis. Higher scores indicate greater satisfaction.

Qualitative Results

Four main themes were identified from the thematic analysis and are described below (see Appendix O for coding example).

Theme 1: Patient's positive engagement and response to the Tovertafel

Staff reported the majority of patients on the ward responded positively to the Tovertafel and were able to engage with it. Staff identified that patients appeared to experience positive affect while using the Tovertafel:

"(We) always have a full table when using the magic table and patients (are) facially bright when using this" (Participant A).

Staff also felt the Tovertafel was beneficial in providing meaningful group activity for patients which generated interest and pleasure. Staff remarked that the Tovertafel helped to facilitate the patients' social engagement with others while taking part in the activity:

"They (patients) enjoy spending time on the Magic Table, it often keeps patients occupied with the company of others and creates conversation…..(the) Magic Table is not used on a daily basis, but on the days it is used, it provides a meaningful activity for variable lengths of time" (Participant E).

Several staff members did acknowledge there can be challenges in engaging participants with the Tovertafel in this acute admissions ward environment and those who were acutely unwell may not find the activity as accessible as others:

"Some (patients) really enjoy the activities, however, it can be difficult to engage some of them due to illness" (Participant B)

Theme 2: Benefits to staff from using the Tovertafel

Participants highlighted several ways in which they felt the Tovertafel also benefited staff. They reported to being generally satisfied at work, but for some, the Tovertafel has enhanced their satisfaction. This was often linked to the perceived benefits to patients:

"I always enjoy my work but have been given job satisfaction with the results that the magic table has given and the response from the patients." (Participant K).

Several staff members suggested the Tovertafel creates a focus for staff to engage patients and it can help them to respond to a distressed patient. Having this additional tool at their disposal was a factor in reducing work-related stress for some staff members:

"Stress levels at work have been reduced as now I am able to involve patients in activities that reduce their stress levels, and this helps with my stress levels" (Participant C)

Staff commonly identified that their stress levels would vary depending on the clinical demands of the ward at the time, however a number of them felt the Tovertafel continued to be beneficial across the varying demands of clinical activity:

"These (staff stress levels) fluctuate according to the level of stress and distress in the ward. However, activities and distraction techniques like this help" (Participant M).

The novelty of a new activity was also a factor in some staff members' feeling of enjoyment in their work, with suggestions that being able to offer a new and engaging activity positively influenced staff as well as patients:

"A pleasure to come to work engage in a different activity" (Participant O).

<u>Theme 3: Opportunities to enhance care without changes to workload</u>

Several staff members reported on instances of the Tovertafel providing opportunities to enhance the care they provide to patients. In particular, the social opportunities the Tovertafel provides have allowed staff to build rapport and better understand their patients, something which can be a particular challenge in an acute admissions ward:

“Staff have observed that when patients are involved in these activities, they respond better to staff interaction. Trust appears to be built” (Participant K).

Some staff members also identified there had been changes in the way in which activities were being viewed on the ward and staff were focussing on engaging patients in them:

“Activities are being well utilised and discussed more, with encouragement for patients to join in” (Participant E)

Staff felt their work duties had not changed over the period of the study and that the introduction of the Tovertafel had not impacted their ability to carry out the other aspects of their roles:

“There seems to have been plenty of time to achieve all my duties” (Participant A)

Staff reported they were able to integrate the use of the Tovertafel into their daily work and fit this around their other clinical responsibilities:

“.. work duties are carried out regardless, however I have tried to incorporate activities and organise time for this around my daily tasks” (Participant M).

Discussion

Our multiple-baseline single-case study results suggest the Tovertafel has the potential to produce beneficial outcomes for some staff members who are using it alongside patients. Most participants demonstrated improvements in burnout, sense of competence and reciprocity items, with all three factors showing effects in the meta-analysis. The effect on shift-by-shift satisfaction ratings were mixed, with participants experiencing both positive and negative changes, and no significant effect was found in this meta-analysis. The qualitative data suggests the Tovertafel has the potential to enhance patient care, improve staff wellbeing and is easy for staff to engage patient in using it.

Particularly important when considering a new intervention, the results do not suggest the Tovertafel increases burnout out among staff. Increased workload is the most significant self-reported cause of workplace stress (Health and Safety Executive 2017), meaning labour-intensive interventions poses the risk of further increasing staff burnout. Staff qualitative reports in this study suggest the Tovertafel does not add significant extra staff workload, but instead provides them with an additional tool which can help enhance their relationships with patients, similar to finding in studies utilising robots in dementia care (Abbott *et al.* 2019).

Eleven of the fourteen individual outcome items which measured burnout factors showed improvement, suggesting the Tovertafel may have potential to reduce burnout in staff. Staff feeling emotionally drained at work appeared to be particularly amenable to improvements, with all but one of the staff in the analysis reporting medium to large improvements in this item. This may be attributed to changes in sense-of-competence and reciprocity (discussed below), however, as the qualitative results suggest the Tovertafel assists staff in developing a better understanding of their patients, an increase in staff empathy may also be a factor in lowering the risk of burnout, as has been seen in other studies investigating the effectiveness of interventions to increase staff empathy (Narme 2018). A measure of staff sense of empathy towards their patients may be a helpful addition in future studies to determine the validity of this theory and better understand how it interacts with burnout factors such as reciprocity.

Six of the nine participants analysed reported improvements in feeling able to offer stimulation for the patients in their care. The results from this sense of competence item are encouraging, given that the patients cared for on this particular ward often have advanced dementias and can struggle to engage with activities. Staff qualitative reports of most patients being able to

access and engage positively with the Tovertafel suggests it may prove a useful tool in helping staff feel able to offer activities to a broad range of patients. This is an important aspect of self-efficacy which, as reported by Duffy *et al.* (2009), can be a significant factor in the risk of burnout, suggesting this aspect of the Tovertafel may be protective for staff wellbeing. However, an objective measure of efficacy in engaging patients would add greater strength to this result, as it would allow a better understanding of the patient experience in this context as well as that of staff. This could be achieved through observational methods, such as Dementia Care Mapping.

Reciprocity items, such as the 'appreciation that adults in your care have for you' item, were less strongly impacted, with six of eleven individual item outcomes demonstrating improvement. However, qualitative reports suggest the Tovertafel can elicit improvements in staff-patient relationships, similar to findings of Swan *et al.* (2018) in their research on iPad use in dementia care, whereby staff feel that they know their patients better. It may be the nature of the setting in this study (an acute ward where patient stays may be as short as a few weeks) limits the changes that can be observed in relationships compared to long-stay facilities. It may also be that the social environment created by the Tovertafel can be replicated by other interventions, but greater understanding of the ‘active components’ of the Tovertafel which create this would be required before we can be confident that these results could be widely replicated. Objective observation tools, such as the Quality of Interactions Schedule or Dementia Care Mapping could be utilised alongside subjective measures of reciprocity to more closely link reciprocity in staff patient relationships to other outcomes.

Another individual outcome item which showed improvement across several participants was the SCID item: “How well do you feel you can engage a person with dementia in creative activities during your normal working day?”. Four participants reported medium to large effect sizes. As other studies have shown, co-constructed creativity can be beneficial for both people living with dementia and staff (Robertson & McCall 2020), this may be a further way in which the Tovertafel and other technologies can help improve staff outcomes.

The results from the token measure of staff satisfaction were mixed, and ultimately add little to our understanding of the impact of the Tovertafel on staff burnout factors. This is at least partly likely to be due to the wording of the question, which could have been more closely linked to the elements of burnout. The token system of data collection was well received by staff and could be used in other busy clinical environments as a method of unobtrusive data collection, but with a more specific question which linked more closely to the burnout factors.

While the results suggest that the Tovertafel can may be beneficial in reducing staff risk of burnout, increasing sense of competence and increasing reciprocity to varying degrees, the nature of burnout and the environment means extraneous variables, in particular, organisational factors affecting burnout, may have impacted the results of the study. Conducting the study in a small ward during a relatively stable period did limit these variables somewhat, however, including measurement of these factors (e.g. workload, availability of resources, satisfaction with renumeration etc.) in future studies and mapping this to changes in burnout would allow for a better understanding of how the impact of the Tovertafel sits within the organisational context and whether it persists as organisational factors shift.

In this study it was not possible to connect the use of the Tovertafel at specific times to the data collection time points (e.g. to record the degree to which the Tovertafel was used in the week preceding each data collection). More closely mapping the use of the Tovertafel to the data collected would allow future studies to better link the intervention use to outcomes and to understand the 'dose' of Tovertafel use which produces benefit.

As an exploratory study, the use of single-case study methodology gives insight into the experience of individuals and highlights areas for future studies to consider, but does mean that the results may not be replicated in other settings or with other participants. Larger scale studies assessing the impact of the Tovertafel on staff well-being are needed before we can be confident that these results represent a replicable effect.

The Tovertafel was able to be applied successfully in this acute setting with high clinical demand, suggesting acceptability of the Tovertafel to both staff, and patients with complex needs. The Tovertafel could likely, therefore, be implemented in other settings, given the challenges of successful use of non-pharmacological interventions in in-patient hospital settings (White *et al.* 2017). The Tovertafel comes at a significant monetary cost, but the price is comparable to that of other interventions, such as the robot seal, PARO (PARO Seal 2020). The Tovertafel also has the advantage (particularly in light of current concerns regarding COVID19 transmission) of only requiring the surface onto which images are projected to be sanitised after use, as opposed to robotic interventions, which often require the cleaning of plush fabrics. Although long-term maintenance of the intervention was not considered in this study, the staff and managers of the ward are keen to continue the use of the Tovertafel as it was used in this study, and ongoing costs of the intervention are minimal.

Strengths and limitations

Strengths of the study include its mixed-method approach, which can be particularly important in early-stage, exploratory research such as this (Vernooij-Dassen & Moniz-Cook 2014). It was possible to identify potential benefits of the Tovertafel beyond those initially anticipated, which can now be expanded upon in future research. The methodology allowed for the understanding of elements of burnout in-depth, at an individual level, in a population which can be challenging to engage, while still allowing for statistical analysis. The study was conducted in a clinically demanding setting, which is often under-represented in the literature (McCausland *et al.* 2019) and where patients needs are complex, suggesting this methodology could also be applied in less clinically challenging settings.

With regards to the limitation of the study, although the individually selected outcome measures contributed to the person-centred nature of this research, this also has the potential to skew the outcome measures towards items which participants perhaps felt more comfortable discussing or felt would show them in a positive light. The selection of personalised outcome measures also relies on a degree of introspection and personal insight in order for the staff participants to select meaningful items with potential for change during the intervention. If participants are avoidant of certain items or lack insight into which items may be of particular interest for them, significant outcomes from the interventions, both positive and negative, may be missed from the analysis. In future, gaining the consent of staff to involve supervisors or managers in the selection of outcome items to provide a degree of objectivity, while maintaining the person-centred approach may help to address this. The researchers in this study have professional backgrounds which differ from those of the participants in the study. This may have influenced the interpretation of the qualitative results and could have been addressed by using a synthesised member check of the analysis, but unforeseen operational issues caused by the COVID19 pandemic prevented this. More prolonged baseline periods would be desirable to allow for the establishment of more stability in the baseline. This always has to be balanced, however, with the pragmatic concerns of maintaining staff engagement and minimising the burden posed by the study. Similarly, the high number of missing data points for some participants placed limitations on the power of the analysis in this study, as PAND is known to be sensitive to the number of data points in each phase (Pustejovsky 2019). The confidence intervals reported in the Phi calculations were mostly quite broad, partly due to the relatively small number of data points suggesting that further analysis on a larger scale and over longer time periods may be required to establish greater confidence in the results reported here.

Although the study was designed to be as practical as possible for staff to complete, it highlights the challenges of collecting data in a busy ward environment. Future studies in similar environments may consider whether the use of technology for data collection improves adherence to the protocol.

Future research

Significantly more research is required before we can confidently understand the potential impact of the Tovertafel and other technology-based non-pharmacological interventions on the staff who implement them. Future studies will want to examine beyond the single-case study methodology to determine the replicability of the results found in this study. Electronic tracking could help to capture data regarding the use of the Tovertafel by each staff member over the course of the study to strengthen the link between use of the intervention and outcome. This could also include measures of fidelity of the use of the Tovertafel (e.g. the extent to which staff are engaged and present with the activity). The addition of an outcome measure such as the Organizational Context Measure (Glisson *et al.* 2008) would allow for better understanding of the extraneous organisational factors which influence the social environment in which future studies may take place. It is important to note that interventions such as the Tovertafel will not prove beneficial to every staff member (exemplified by Participant M), just as they will not be beneficial to every person living with dementia. Future studies may determine if particular staff traits allow them to benefit more readily from specific interventions. Studies should seek to explore these factors across a variety of settings, cultures and professions by studying outcomes of staff and people living with dementia side-by-side. This could be achieved by including observational techniques, which are centred on the experience of the person living with dementia (such as Dementia Care Mapping) alongside measures of staff burnout factors. Only by understanding both staff and patient experiences at a systemic level within the same study, can we begin to understand the full impact and challenges of applying technological interventions to dementia care.

Conclusions and Clinical Implications

It is vital to consider staff wellbeing when implementing non-pharmacological interventions in dementia care, as this can benefit the wellbeing of the workforce and the efficacy of the intervention. This study offers a first insight into the potential of the Tovertafel system to reduce staff burnout, improve staff sense of competence and improve relationships between staff and the patients they care for, without adding to staff burden. As interventions such as this continue to be evaluated, the impact on staff should be considered alongside the outcome for patients

in order to understand the effect of technology-based non-pharmacological interventions on the wider system.

Conflict of interest

None. The authors have no links to companies which are developing and/or selling the Tovertafel.

Author roles

F. Beaton, A. Guzman and G. Bowie designed the study. F. Beaton carried out the data collection and analysis. F. Beaton wrote the initial draft of the manuscript and all authors were involved in the critical revisions of the manuscript.

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Appendix A - Author Guidelines for International Psychogeriatrics Journal

Instructions for authors

International Psychogeriatrics

Please read these instructions carefully before submitting articles. Articles which are not prepared in accordance with these guidelines will be returned to authors unreviewed.

Scope and contributions
International Psychogeriatrics is written by and for those doing clinical, teaching, and research work concerning mental health of older people. It is the official journal of the International Psychogeriatric Association (IPA) and is published by Cambridge University Press. Although it is concerned primarily with psychogeriatrics, the journal welcomes contributions from all concerned with the field of mental health and aging. Original research papers are particularly sought.

Contributions include original research articles, reviews of the literature, brief reports, letters to the editor, and invited commentaries and guest editorials. Apart from commentaries and editorials, which are commissioned, contributions to *International Psychogeriatrics* are prepared and submitted by authors. Papers that are not rejected after initial review by the Editor-in-Chief or his representative, are reviewed by at least two expert reviewers selected by the Editor-in Chief. The journal is published twelve times per annum. Submission of a paper implies that it is neither under consideration for publication elsewhere, nor previously published. Manuscripts must be formatted double-spaced with ample margins on all sides and the pages should be numbered. Please leave a spare line between paragraphs to enable typesetters to identify paragraph breaks without ambiguity. *International Psychogeriatrics* uses the spelling of American English. Manuscripts written by those whose primary language is not English should be edited carefully for language prior to submission.

The journal does not publish papers whose sole focus is the validation of translated instruments that have previously been well assessed and validated in English or another language. These articles are better placed in a relevant National, rather than an International, journal. (A rare exception may be when social or cultural issues of international significance are clearly involved.) Case reports may be considered for publication only as Letters to the Editor.

Special Note:
Since this is *International Psychogeriatrics*, the authors should seek to highlight international significance of their article in terms of clinical practice, training, or research in different parts of the world. The authors are also advised to go over recent issues of *International Psychogeriatrics* to review papers on related topics, and add how their new submission advances the field further.

Submission of manuscripts

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When submitting your manuscript you will need to supply each of the following:

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- The manuscript as a text file in MS Word format (font Arial, minimum size 11)
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- All figures in TIFF or JPEG format.

If the paper reports the results of a randomized controlled trial please ensure that it conforms to our requirements listed below under the heading 'Submission of randomized clinical trials' section of these instructions. If the research was paid for by a funding organization, the cover letter must contain the following three statements (this information does not have to be included in the manuscript itself but only in the cover letter). If the research was not paid for by a funding organization only the third statement is required:

- That the authors have not entered into an agreement with the funding organization that has limited their ability to complete the research as planned and publish the results.
- That the authors have had full control of all the primary data.
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All papers judged to be appropriate for further review will be assessed by two or more reviewers**.** The Editor-in-Chief's decision to accept, reject or request revision of the paper for publication will be final. The abstract and author details will be seen by prospective reviewers of the manuscript. Authors should suggest the names and contact information of experts qualified to review the work, but the Editor-in-Chief is not obliged to follow these suggestions. Papers must bear the authors' names, titles (e.g., Dr, Professor, etc.), affiliation(s), and address(es). This information will be seen by reviewers. Reviewers' names will not be supplied to authors unless a reviewer asks to be so identified. Authors will be provided with a copyright transfer form to sign after acceptance of the manuscript, consenting to publication of the paper in *International Psychogeriatrics*.

All submissions are acknowledged electronically upon receipt. Most authors can expect to receive an initial decision regarding their paper together with referees' reports within 8 to 10 weeks of submission. Authors who have received no further communication 90 days after acknowledgment of receipt of their article should contact ipaj-ed@cambridge.org.

Article Types

Regular Research Articles: Regular Research Articles are original papers demonstrating the results of scientific studies, based on empirical data. The text of the article should contain no more than 5,000 words, in addition to an abstract of 300 words and up to 60 references. This word count includes only the main body of text (i.e., not abstract, references, tables, or figures).

Brief Reports: This category allows for articles that are shorter than original research but have the same style and may be used to report new and innovative research and/or significant (hot topics). Brief reports are also peer reviewed. They should be of 2,000 words or less and include no more than two figures or tables, no more than 10 references, and have an abstract of no more than 250 words, **without** structured sub-headings.

Reviews of the Literature: Authors intending to submit a literature review should check recent issues of *International Psychogeriatrics* to ensure that no review of the topic they propose to discuss has been published in the journal in recent times. Review articles should be of 6,000 words or less, have an abstract of up to 300 words, and may have up to 80 relevant references. Authors contemplating the submission of a literature review article are welcome to contact the editor to discuss the appropriateness of the topic prior to submission (ipaj-ed@cambridge.org). Literature reviews should have an abstract.

Letters to the Editor: Reader's letters will be considered for publication. Letters should be no longer than 750 words, with no more than 1 table or figure, and no more than 10 references. No abstract is required.

Guest Editorials and *Invited Commentaries* are commissioned by the editor.

Organization and style of manuscripts

Title page and corresponding author: Each article must have a title page with the title of the article, a list of all authors and their titles, affiliations and addresses. Each author must select only ONE country as their location. Author qualifications should not be listed as these are not published in the journal. The title page should explicitly identify the author to whom correspondence about the study should be addressed and that author's email address, telephone number, fax number and postal address must be clearly stated.

Abstract (Structured): Abstracts for original research and reviews should be structured and incorporate the following headings: Objectives, Design, Setting, Participants, Intervention (if any), Measurements, Results, and Conclusions. Abstracts should communicate the primary findings and significance of the research. They should not exceed 300 words in length. Abstracts for brief reports should not exceed 300 words and should **not** be structured with sub-headings.

Keywords: Under this heading and beneath the abstract, please list up to 8 words for the purpose of indexing.

Running title: This should contain no more than 50 characters including spaces.

Introduction: Briefly state the relevant background to the study to provide the necessary information and context to enable non-specialists to appreciate the objectives and significance of the paper. Most introductions to articles received for review are too long.

Methods: Materials and procedures should be described in sufficient detail to enable replication. Any statistical procedures used should be outlined and their use should be justified here. Results should not be included in the Method(s) section. If statistical procedures are used, they should be described here in adequate detail. Choice of statistical technique should be justified including some indication of the appropriateness of the data for the technique chosen. Adequacy of the sample size for the statistical technique(s) used must be addressed. If appropriate, a description of the statistical power of the study should be provided. If multiple univariate significant tests are used, probability values (p-values) should be adjusted for multiple comparisons, or alternatively a multivariate test should be considered. Significance results (p values) must be presented with accompanying statistics.

Further advice about statistics and *International Psychogeriatrics* can be found in the following article: Chibnall, J. (2000) Some basic issues for clinicians concerning things statistical. *International Psychogeriatrics*, 12, 3-7. The following article may also be of assistance to intending contributors: Chibnall J.T. (2004). Statistical audit of original research articles in *International Psychogeriatrics* for the year 2003. *International Psychogeriatrics* 16, 389-396. Both of these are available at the *International Psychogeriatrics* website by following the above links.

Results: This section may contain subheadings. Authors should avoid mixing discussion with the results. Sample sizes should be delineated clearly for all analyses. Some indicator of variability or sampling error should be incorporated into the reporting of statistical results (e.g. standard deviation). Wherever possible an indicator of effect size (e.g. Cohens d, η^2, Cramers V, 95% confidence interval) should be reported in addition to p values. If multiple univariate statistical tests are used p values should be adjusted for multiple comparisons or alternatively a multivariate test should be used. Obtained statistical values for tests should be reported with degrees of freedom (e.g. t, F, χ^2). Terms such as prevalence, population, or control group, should be used appropriately in the scientific sense.

Discussion: Interpretation of the results with respect to the hypothesis(es) and their significance to the field should be discussed here. Results should be interpreted in the light of the size of the effect found and the power of the study to detect differences. Any methodological and other weaknesses of the study should be outlined, including limitations imposed by sample size. Careful consideration of the conclusion(s) for accuracy and alternative interpretation, and possible conflicts or resolution of conflicts in the field is encouraged. Limited speculation and directions for future research can be included.

Conflict of interest declaration: **This section must be completed**. This should follow the discussion and precede the references. Where there is no conflict of interest perceived to be present the heading Conflict of Interest should be included with the single word "none" underneath it. For full details see below.

Description of authors' roles: **This section must be completed if the paper has two or more authors**. It should contain a very brief description of the contribution of each author to the research. Their roles in formulating the research question(s), designing the study,

carrying it out, analysing the data and writing the article should be made plain. For example: H. Crun designed the study, supervised the data collection and wrote the paper. M. Bannister collected the data and assisted with writing the article. N. Seagoon was responsible for the statistical design of the study and for carrying out the statistical analysis.

Acknowledgements: Any acknowledgements other than conflict of interest declarations in regard to sponsorship should be listed briefly here. Acknowledgements imply that the person/s mentioned have approved the citation of their name/s in the paper.

References: For review papers, no more than 75 articles that have been published or are in press should be cited; for regular research articles no more than 60 references, for brief reports no more than 10 references, for commentaries and editorials no more than 10 references, and for letters no more than 10 references. Unpublished data, personal communications, and manuscripts submitted for publication should be cited in the text and the supporting material submitted with the manuscript. *International Psychogeriatrics* uses the Harvard referencing system. Within the text of each paper journal articles should be cited in the style (Smith and Jones, 1999). Where an article quoted in the body of the text has more than two authors the term "et al." should be employed, i.e., (Smith et al., 1999). Text citations of multiple articles should be separated by semicolons, i.e., (Smith and Jones, 1999; Smith et al., 1999). At the end of each paper, all cited references should be listed alphabetically in the style indicated below. If the Digital Object Identifier (doi) is known, it should be added to the reference.

Reference examples:

For a journal article: **Smith, J., Jones, W. I. and Doe, J. T.** (1996). Psychogeriatrics for pleasure and profit: an expanding field. International Journal of Unreproducible Results, 3, 240–242. doi:12.3456/S123456789.

For a book: **Smith, J.A., Brown, P.Q., Jones, H.A. and Robinson, D.V.** (2001). Acute Confusional States. New York: Cambridge University Press. For a book chapter. **Park, K., Tiger, B. and Runn, F.** (1999). Psychogeriatrics in context. In G.Verdi and A. Boito, (Eds.) New Medical Specialties (pp. 240–260). Cambridge: Cambridge University Press.

Where an article or book chapter has more than six authors only the first author's name should be given followed by the words "***et al***.".

For further examples of reference style see papers in recent issues of *International Psychogeriatrics*.

Figures/Tables: The manuscript should contain no more than five figures or tables (no more than two figures or tables for brief reports). The copies submitted with the manuscript must be of sufficient quality to enable reviewers to evaluate the data. The journal has a small budget to permit some color to be printed in come issues but authors wishing to publish figures requiring color to communicate the data may be required to pay some or all the additional cost.

Figure/Table legends: Each caption should begin with a brief description of the conclusion or observation provided in the figure. These should be submitted as a separate section after the References.

Supplementary material: *International Psychogeriatrics* has the facility to include supplementary materials (figures, tables, appendices, any non-English sections, and other material not suitable for inclusion in the print version of the journal) with the electronic version of individual papers at https://www.cambridge.org/core/journals/international-psychogeriatrics. This renders such supplementary material accessible without clogging the journal with materials that will be of interest to only a small minority of readers.

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- You wish to link to additional information which due to its nature does not lend itself to print media (examples- full data sets, movie or sounds files etc.)
- The Editor of the Journal has requested that you extract certain information from the original article in order to allow for space constraints of the print version.
- You have requested additional material to be available to accompany an article that does not normally allow such material to be included (examples – sections not written in the English language, tables to accompany a correspondence article).

N.B. Please note that no copyediting or quality assurance measures will be undertaken on supplementary material (other than to ensure that the file is intact). The authors therefore warrant that the supplementary material that they submit is in a suitable format for publication in this manner. The material shall be published online in exactly the form that it is supplied.

Submitting Supplementary Material

Please follow these instructions to submit supplementary material:

- Each supplementary file must be supplied as a separate file. Do not supply this material as part of the file destined for publication in the print journal.
- Each supplementary file must have a clear title (for example, Supplementary Figure 1).
- Provide a text summary for each file of no more than 50 words. The summary should describe the contents of the file. Descriptions of individual figures or tables should be provided if these items are submitted as separate files. If a group of figures is submitted together in one file, the description should indicate how many figures are contained within the file and provide a general description of what the figures collectively show.
- The file type and file size in parentheses.
- Ensure that each piece of supplementary material is clearly referred to at least once in the print version of the paper at an appropriate point in the text, and is also listed at the end of the paper before the reference section.

Word limits: The text of Review articles should not exceed 6,000 words, Regular research articles 5,000 words, brief reports 2000 words, and letters to the editor 750 words. The text excludes title page, abstract, acknowledgements, references, tables, and figures. Articles may contain supplementary material which is published online only.

Format and file size: File sizes should be as small as possible in order to ensure that users can download them quickly.

Images should be a maximum size of 640 x 480 pixels at a resolution of 72 pixels per inch.

Authors should limit the number of files to under ten, with a total size not normally exceeding 3 MB. Sound/movie files may be up to 10 MB per file; color PDFs/PowerPoint may be up to 5 MB per file; all other general file types may be up to 2 MB per file but most files should be much smaller.

We accept files in any of the following formats (if in doubt please enquire first):

MS Word document (.doc) , Adobe Acrobat (.pdf), Plain ASCII text (.txt), Rich Text Format (.rtf), WordPerfect document (.wpd), HTML document (.htm), MS Excel spreadsheet (.xls), GIF image (.gif), JPEG image (.jpg), TIFF image (.tif), MS PowerPoint slide (.ppt), QuickTime movie (.mov), Audio file (.wav), Audio file (.mp3), MPEG/MPG animation (.mpg)

If your file sizes exceed these limits or if you cannot submit in these formats, please seek advice from the editor handling your manuscript.

Submission of papers reporting randomized controlled trials

In order to ensure the public availability of the results of randomized controlled trials, the International Committee of Medical Journal Editors has suggested that all such trials should be registered. In common with many leading medical journals *International Psychogeriatrics* has decided to follow this policy. We will not review any paper submitted to us reporting a randomized clinical trial unless the trial was registered in a public trial registry from the date it commenced recruitment.

All manuscripts reporting randomized controlled trials should have the following sent with them or they will be returned to the authors.

- A check list and flow chart in accordance with the CONSORT guidelines which can be found at http://www.consort-statement.org. Please send in the checklist as a supplementary file and include the flow chart as Figure 1 in the manuscript.
- The trial protocol is to be submitted as a supplementary file. This will not be published but it is needed to appraise and peer review the paper. If the protocol is already published, a copy of that paper should be submitted.
- The registration number of the trial and the name of the trial registry in which it was registered. Please add these to the last line of the paper's structured abstract. Trials must have been registered in a public trials registry at or before the onset of enrolment to be considered for publication in *International Psychogeriatrics*. Our criteria for a suitable public trial registry are: free to access; searchable; identification of trials by unique number; free or minimal cost for registration; validation of registered information; inclusion of details to identify the trial and the investigator within the registered entry

(including the status of the trial); research question; methodology; intervention; and funding and sponsorship disclosed.

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Conflict of interest occurs when authors have interests that **might** influence their judgement inappropriately, regardless of whether that judgement is influenced inappropriately or not. *International Psychogeriatrics* aims to conform to the policies of the World Association of Medical Editors in regard to conflict of interest. For full details please see the website http://www.wame.org/wamestmt.htm#fundres. To this end all authors must disclose potential conflicts of interest so that others may be aware of their possible effects. Specifically, under the heading conflict of interest, all articles must detail:

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A description of any sponsor's role(s) in the research (e.g., formulation of research question(s), choice of study design, data collection, data analysis and decision to publish).

Information about any financial relationship between any author and any organization with a vested interest in the conduct and reporting of the study. For example, in a study on the effects of a drug made by Bigpharma which directly competes with another drug made by Megadrug a declaration might say "Jane Smith has received research support and speaker's honoraria from Bigpharma and has received financial assistance from Megadrug to enable her attend conferences."

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Supply of author-generated artwork

Monochrome line subject illustrations supplied in digital form
Macromedia Freehand, Adobe Illustrator and Adobe Photoshop are the preferred graphics packages. Before submitting your artwork, please do the following:

Where possible, please supply illustrations as TIFF or EPS files (300 dpi). When submitting EPS files you must convert your text within the file to artwork/outlines. If your EPS file contains a scanned image, you must ensure that you supply a full EPS, i.e. binary data. Do not supply PostScript files. PostScript files cannot be included within our integrated page make-up system, or worked on in any way. For best results please save your files as TIFF or EPS files. If files cannot be supplied in this way other formats can be handled (although we do not guarantee to use them).

Draw or scan line artwork to finished size with appropriate line weights and typefaces.

Indicate the file format (e.g. TIFF or EPS), the graphics software that you have used in originating the artwork files (e.g. Freehand 7.0, Illustrator 8.0, etc.) and the computer operating system used (e.g. Mac OS 8.6, Windows NT).

Supply a laser print of all figures. List the name and version of the artwork package used and the names and libraries of fonts used in the artwork or EPS files.

Pattern fills and tints

Artwork packages do not always generate pattern fills for output on image/platesetters. Imagesetters will interpret them differently from your Mac or PC and the result often looks pixelated or blocked. Where possible, use PostScript fills, custom fills and conventional tints. 9

PostScript fills frequently do not display well on screen but they do print out correctly. It is best to avoid the use of complex or very detailed tints, patterns and symbols. These seldom reproduce satisfactorily when reduced to fit the page and when used in a caption or legend may be completely illegible when represented on a screen (for example during page make-up, or on the Web) or when output on low-quality CUP artwork instructions.doc 2 laser printers. Supplying as TIFF or EPS files (see above) alleviates this problem.

Please therefore:

- Use only the tints, patterns and symbols shown here.
- Use conventional fills: solids, tints, lines or cross-hatching.
- Use a PostScript fill if possible.
- Do not use a screen value above 133 lpi. Generally, 100 lpi is better (even when scanned at high resolution finer tints do not reproduce satisfactorily when reduced).
- If possible, use just one kind of screen (line angle or dot shape) and one screen value throughout the document.
- Do not use pattern fills from a graphics program, as these are usually bitmap patterns, which do not output adequately to plate/image setters.
- Do not use color tints, even if the figure is intended for monochrome printing; use black/white/greyscale.

- Do not use .hairline. line widths in graphics packages.

Monochrome halftone subjects

Figures composed of (hard copy) photographs should be unscreened glossy prints presented at publication scale; each component part should be named with a lower-case letter. Photographic artwork is numbered as part of the sequence of figures, not as separate plates.

If supplying these in digital form, your repro house should follow these instructions:

- Scanning: Scan at a resolution that is around twice the intended screen value; for example scan at 300 dpi for 133 or 150 screen.
- Dot range (halftones only): This is the term we use to describe the highlight/white area and shadow/black areas within a printed image. To prevent the heavy or dark areas of your halftones from filling in or the light areas being washed out we specify a dot range that allows for gains or losses during the process to lithographic printing. Pre-set the dot range at 1% highlight to 96% shadow where possible, we will check your files before outputting as a safeguard.
- Data files: Supply data as TIFF files; if you wish to compress them, use lossless compression software such as the LZW compression package.
- Laser proofs: Supply a good quality laser proof of all figures. List the name and version of the artwork package used and the names and libraries of fonts used in the artwork. If we are unable to use your electronic file, we can scan in the laser proof as an alternative until a revised file can be supplied.
- Line & tone combination: Files scanned as line & tone combination should be scanned at a higher resolution than a standard halftone to ensure better type/line quality, for example, 600 dpi.

Color halftone or line subjects

Do not submit line subject drawings with colored tints unless the figure is required as a color plate; use only black/white/greyscale.

If supplying color subjects in digital form, submit as TIFF or EPS files and choose CMYK color mode when saving your scans. If you supply files as RGB we need to convert them to the CMYK printing process before we can print, this usually results in a slight change of the color values; therefore all color correction must be carried out in CMYK mode on your machine.

General notes

Following acceptance of a manuscript the contact author should receive proofs within 1-12 weeks. They also will be required to complete and forward a copyright form and authors' checklist both of which will be forwarded to the corresponding author by email when the article is accepted.

The average time from an article being accepted to being e-published ahead of print as a First View article is 35 days, provided authors return proofs promptly. E-publication generates a doi number and counts as full publication for citation purposes.

Editorials and commentaries are commissioned by the editor.
Reviewers who reviewed papers in the previous calendar year will be acknowledged in the journal each year. *International Psychogeriatrics* no longer publishes an annual index as modern computerised search techniques have rendered annual hard copy indices obsolete.
Contributors should refer to recent issues of the journal for examples of formatting (abstracts, headings, references, tables, etc.).

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Appendix B - Systematic Review Critical Appraisal

	Francis et al (2020	Hatakeyama et al (2010)	Davison et al (20 6)	Rouse et al (2019)	Yu et al (2015	Yu et al (2019)	Loi et al 2017	Gustafsson et al (2015)	Jøranson et al (2015)	Lane et al (2016)	Liang et al (2017)	Libin et al (2004)	Marti et al (2006)	Moyle et al (2016)	Moyle et al (2017)	Moyle et al (2018)	Moyle et al (2019)	Petersen et al (2017)	Thodberg et al (2015)	Valenti Soler et al (2015)
RANDOMISED CONTROL TRIALS																				
1. Was true randomization used for assignment of participants to treatment groups?		U	Y		U	Y			U		Y				Y			N	U	N
2. Was allocation to treatment groups concealed?		U	U		U	Y			U		Y				Y			U	U	U
3. Were treatment groups similar at the baseline?		Y	Y		U	Y			Y		Y				Y			Y	U	U
4. Were participants blind to treatment assignment?		N/A	N/A		N/A	N/A			N/A		N/A				N/A			N/A	N/A	N/A
5. Were those delivering treatment blind to treatment assignment?		N/A	N/A		N/A	N/A			N/A		N/A				N/A			N/A	N/A	N/A
6. Were outcomes assessors blind to treatment assignment?		U	Y		Y	Y			U		N				Y			U	U	Y
7. Were treatment groups treated identically other than the intervention of interest?		U	Y		Y	Y			Y		U				Y			Y	Y	Y
8. Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed?		U	U		U	U			U		N				U			U	U	N
9.Were participants analyzed in the groups to which they were randomized?		U	U		Y	Y			Y		U				Y			U	U	U
10. Were outcomes measured in the same way for treatment groups?		Y	Y		Y	Y			Y		Y				Y			Y	Y	Y
11. Were outcomes measured in a reliable way?		Y	Y		Y	U			Y		Y				U			U	Y	U
12. Was appropriate statistical analysis used?		Y	Y		Y	Y			Y		Y				Y			Y	Y	Y

Y = Yes ; N= No ; U= Unclear ; N/A = Not applicable

	Francis et al (2020)	Hatakeyama et al (2010)	Davison et al (2016)	Rouse et al (2019)	Yu et al (2015)	Yu et al (2019)	Loi et al (2017)	Gustafsson et al (2015)	Jøranson et al (2015)	Lane et al (2016)	Liang et al (2017)	Libin et al (2004)	Marti et al (2006)	Moyle et al (2016)	Moyle et al (2017)	Moyle et al (2018)	Moyle et al (2019)	Petersen et al (2017)	Thodberg et al (2015)	Valenti Soler et al (2015)
13. Was the trial design appropriate, and any deviations from the standard RCT design (individual randomization, parallel groups) accounted for in the conduct and analysis of the trial?		U	Y		U	Y			U		Y				Y			U	U	U
QUASI-EXPERIMENTAL STUDIES																				
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)?	Y			Y			Y	Y		Y		Y								
2. Were the participants included in any comparisons similar?	Y			Y			Y	Y		Y		Y								
3. Were the participants included in any comparisons receiving similar treatment/care, other than the exposure or intervention of interest?	Y			Y			Y	Y		Y		Y								
4. Was there a control group?	N			N			N	N		N		N								
5. Were there multiple measurements of the outcome both pre and post the intervention/exposure?	N			N			N	Y		Y		N								
6. Was follow up complete and f not, were differences between groups in terms of their follow up adequately described and analyzed?	U			U			U	Y		U		U								
7. Were the outcomes of participants included in any comparisons measured in the same way?	Y			Y			Y	Y		Y		Y								
8. Were outcomes measured in a reliable way?	Y			Y			Y	Y		Y		Y								

Y = Yes ; N= No ; U= Unclear ; N/A = Not applicable

	Francis et al (2020)	Hatakeyama et al (2010)	Davison et al (2016)	Rouse et al (2019)	Yu et al (2015)	Yu et al (2019)	Loi et al (2017	Gustafsson et al (2015)	Jøranson et al (2015)	Lane et al (2016)	Liang et al (2017)	Libin et al (2004)	Marti et al (2006)	Moyle et al (2016)	Moyle et al (2017)	Moyle et al (2018)	Moyle et al (2019)	Petersen et al (2017)	Thodberg et al (2015)	Valenti Soler et al (2015)
9. Was appropriate statistical analysis used?	Y			Y			Y	Y		Y		Y								
QUALATATIVE STUDIES																				
1. Is there congruity between the stated philosophical perspective and the research methodology?	U		U	U				U						Y		U	U			
2. Is there congruity between the research methodology and the research question or objectives?	Y		Y	Y				Y						Y		Y	Y			
3. Is there congruity between the research methodology and the methods used to collect data?	Y		Y	Y				Y						Y		Y	Y			
4. Is there congruity between the research methodology and the representation and analysis of data?	U		N	U				Y						Y		Y	Y			
5. Is there congruity between the research methodology and the interpretation of results?	Y		Y	U				Y						U		Y	Y			
6. Is there a statement locating the researcher culturally or theoretically?	N		N	N				N						N		Y	Y			
7. Is the influence of the researcher on the research, and vice- versa, addressed?	N		N	N				N						N		N	N			
8. Are participants, and their voices, adequately represented?	U		U	U				U						U		Y	Y			
9. Is the research ethical according to current criteria or, for recent studies, and is there evidence of ethical approval by an appropriate body?	Y		Y	Y				Y						Y		Y	Y			

Y = Yes ; N= No ; U= Unclear ; N/A = Not applicable

	Francis et al (2020)	Hatakeyama et al (2010)	Davison et al (2016)	Rouse et al (2019)	Yu et al (2015)	Yu et al (2019)	Loi et al (2017	Gustafsson et al (2015)	Jøranson et al (2015)	Lane et al (2016)	Liang et al (2017)	Libin et al (2004)	Marti et al (2006)	Moyle et al (2016)	Moyle et al (2017)	Moyle et al (2018)	Moyle et al (2019)	Petersen et al (2017)	Thodberg et al (2015)	Valenti Soler et al (2015)
10. Do the conclusions drawn in the research report flow from the analysis, or interpretation, of the data?	Y		Y	Y				Y						Y		Y	Y			
CASE SERIES STUDIES																				
1.Were there clear criteria for inclusion in the case series?								Y						Y						
2. Was the condition measured in a standard, reliable way for all participants included in the case series?								Y						Y						
3. Were valid methods used for identification of the condition for all participants included in the case series?								U						U						
4. Did the case series have consecutive inclusion of participants?								N						N						
5. Did the case series have complete inclusion of participants?								N						N						
6. Was there clear reporting of the demographics of the participants in the study?								N						U						
7. Was there clear reporting of clinical information of the participants?								U						Y						
8. Were the outcomes or follow up results of cases clearly reported?								Y						Y						
9. Was there clear reporting of the presenting site(s)/clinic(s) demographic information?								N						U						
10. Was statistical analysis appropriate?								U						Y						

Y = Yes ; N= No ; U= Unclear ; N/A = Not applicable

	Francis et al (2020)	Hatakeyama et al (2010)	Davison et al (2016)	Rouse et al (2019)	Yu et al (2015)	Yu et al (2019)	Loi et al (2017	Gustafsson et al (2015)	Jøranson et al (2015)	Lane et al (2016)	Liang et al (2017)	Libin et al (2004)	Marti et al (2006)	Moyle et al (2016)	Moyle et al (2017)	Moyle et al (2018)	Moyle et al (2019)	Petersen et al (2017)	Thodberg et al (2015)	Valenti Soler et al (2015)
CASE REPORT STUDIES																				
1. Were patient's demographic characteristics clearly described?													N							
2. Was the patient's history clearly described and presented as a timeline?													N							
3. Was the current clinical condition of the patient on presentation clearly described?													U							
4. Were diagnostic tests or assessment methods and the results clearly described?													Y							
5. Was the intervention(s) or treatment procedure(s) clearly described?													Y							
6.Was the post-intervention clinical condition clearly described?													U							
7. Were adverse events (harms) or unanticipated events dentified and described?													U							
8. Does the case report provide takeaway lessons?													Y							

Y = Yes ; N= No ; U= Unclear ; N/A = Not applicable

Appendix C - Systematic review RE-AIM Analysis

	Francis et al (2020)	Hatakeyama et al (2010)	Davison et al (2016)	Rouse et al (2019)	Yu et al (2015)	Yu et al (2019)	Loi et al (2017)	Gustafsson et al (2015)	Jøranson et al (2015)	Lane et al (2016)	Liang et al (2017)	Libin et al (2004)	Marti et al (2006)	Moyle et al (2016)	Moyle et al (2017)	Moyle et al (2018)	Moyle et al (2019)	Petersen et al (2017)	Thodberg et al (2015)	Valent Soler et al (2015)
REACH																				
1. Exc us on Cr ter a (% exc uded or character st cs)	Y	N	Y	Y	Y	Y	N	N	N	N	Y	N	N	N	N	Y	Y	Y	N	Y
2. Percent nd v dua s who part c pate, based on va d denom nator (not of vo unteers who nd cate nterest)	N	N	Y	N	N	N	N	N	Y	N	N	N	N	N	N	N	N	N	N	Y
3. Character st cs of part c pants compared to non part c pants or to target popu at on	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
4. Use of qua tat ve methods to understand reach and/or recru tment	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EFFECTIVENESS																				
5. Measure of pr mary outcome w th or w/o compar son to a pub c hea th goa (e.g. HP 2N2N goa s, exerc se 3N m n/day; eat 5 Fru ts &Vegg es)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
6. Measure of broader outcomes (e.g., other outcomes, measure of QoL or potent a negat ve outcome) or use of mu t p e cr ter a	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	N	Y	Y	N	N	Y	Y	Y
7. Measure of robustness across subgroups (e.g. moderat on ana yses)	N/A	N	N	N	N	N	N/A	N	N	N/A	N	N/A	N/A	N/A	N	N/A	N/A	Y	N	N

Y = Yes ; N=No; N/A= Not applicable

	Francis et al (2020)	Hatakeyama et al (2010)	Davison et al (2016)	Rouse et al (2019)	Yu et al (2015)	Yu et al (2019)	Loi et al (2017)	Gustafsson et al (2015)	Jøranson et al (2015)	Lane et al (2016)	Liang et al (2017)	Libin et al (2004)	Marti et al (2006)	Moyle et al (2016)	Moyle et al (2017)	Moyle et al (2018)	Moyle et al (2019)	Petersen et al (2017)	Thodberg et al (2015)	Valent Soler et al (2015)
8. Measure of short term attr t on (%) and d fferent a rates by pat ent character st cs or treatment cond t on	N	N	Y	N	N	N	N	N	Y	N	Y	N	N/A	N/A	Y	N/A	N/A	N	N	Y
9. Use of qua tat ve methods/data to understand outcomes	Y	N	Y	Y	N	N	N	Y	N	N	Y	N	Y	Y	N	Y	Y	N	N	N
ADOPTION -SETTING LEVEL																				
10. Sett ng Exc us ons (% or reasons)	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	Y	N	Y	N	N	N
11. Percent of sett ngs approached that part c pate (va d denom nator)	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	Y	N	N	N	N	N
12. Character st cs of sett ngs part c pat ng (both compar son and ntervent on) compared to e ther: non part c pants or some re evant resource data	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
13. Use of qua tat ve methods to understand adopt on at sett ng eve	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
ADOPTION STAFF LEVEL																				
14. Staff Exc us ons (% or reasons)	N	N	N	N/A	N	N	N	N	N	N	N	N	N	N	N	Y	N/A	N	N	N
15. Percent of staff nv ted that part c pate	N	N	N	N/A	N	N	Y	Y	N	N	N	N	N	N	N	N	N/A	N	N	N
16. Character st cs of staff part c pants vs. non part c pat ng staff or typ ca staff	N	N	N	N/A	N	N	N	N	N	N	N	N	N	N	N	N	N/A	N	N	N

Y = Yes ; N=No; N/A= Not applicable

	Francis et al (2020)	Hatakeyama et al (2010)	Davison et al (2016)	Rouse et al (2019)	Yu et al (2015)	Yu et al (2019)	Loi et al (2017	Gustafsson et al (2015)	Jøranson et al (2015)	Lane et al (2016)	Liang et al (2017)	Libin et al (2004)	Marti et al (2006)	Moyle et al (2016)	Moyle et al (2017)	Moyle et al (2018)	Moyle et al (2019)	Petersen et al (2017)	Thodberg et al (2015)	Valent Soler et al (2015)
17. Use of qua tat ve methods to understand staff part c pat on	Y	N	N	N/A	N	N	N	Y	N	Y	N	N	N	N	N	Y	N/A	N	N	N
IMPLEMENTATION																				
18.Percent of perfect de very or ca s comp eted, etc. (e.g., adherence or cons stency)	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N/A	N	N	N
19. Adaptat ons made to ntervent on dur ng study	Y	N	N	Y	N	N	N	N	N	N	N	N	N	N	N	N	N/A	N	N	N
20. Cost of ntervent on (t me or money)	N	N	Y	N	N	N	N	N	N	N	N	N	N	N	N	Y	Y	Y	N	N
21. Cons stency of mp ementat on across staff/t me/sett ngs/subgroups (not about d fferent a outcomes, but process)	Y	N	N	N	N	N	N	Y	Y	N/A	N	N	N	N	N	N	N/A	N	N	N
22. Use of qua tat ve methods to understand mp ementat on	N	N	N	Y	N	N	N	N	N	N	N	N	N	N	N	Y	Y	N	N	N
MAINTENANCE INDIVIDUAL LEVEL																				
23. Measure of pr mary outcome (w th or w/o compar son to a pub c hea th goa) at ≥ 6mo fo ow up after f na ntervent on contact	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
24. Measure of broader outcomes or use of mu t p e cr ter a at fo ow up (e.g., measure of QoL or potent a negat ve outcome) at fo ow up	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

Y = Yes ; N=No; N/A= Not applicable

	Francis et al (2020)	Hatakeyama et al (2010)	Davison et al (2016)	Rouse et al (2019)	Yu et al (2015)	Yu et al (2019)	Loi et al (2017	Gustafsson et al (2015)	Jøranson et al (2015)	Lane et al (2016)	Liang et al (2017)	Libin et al (2004)	Marti et al (2006)	Moyle et al (2016)	Moyle et al (2017)	Moyle et al (2018)	Moyle et al (2019)	Petersen et al (2017)	Thodberg et al (2015)	Valent Soler et al (2015)
25. Robustness data someth ng about subgroup effects over the ong term	N/A	N	N	N	N	N	N/A	N/A	N	N	N	N/A	N/A	N/A	N	N/A	N/A	N	N	N
26. Measure of ong term attr t on (%) and d fferent a rates by pat ent character st cs or treatment cond t on	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
27. Use of qua tat ve methods data to understand ong term effects	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
MAINTENANCE SETTING LEVEL																				
28. If program s st ongo ng at ≥ 6 month post study fund ng	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
29. If and how program was adapted ong term (wh ch e ements reta ned AFTER program comp eted)	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
30. Some measure/d scuss on of a gnment to organ zat on m ss on or susta nab ty of bus ness mode	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N
31. Use of qua tat ve methods data to understand sett ng eve nst tut ona zat on	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	N

Y = Yes ; N=No; N/A= Not applicable

Appendix D- Empirical Study Proposal

A mixed-method multiple-baseline single-case study exploring the impact of the Tovertafel (Magic Table) on staff burnout in an acute dementia care hospital ward.

Study Protocol
Version 2

31/05/2019

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Background

Scottish policy has highlighted the vitally important role which health and social care staff play in ensuring that people who are diagnosed with dementia can 'live well with dementia'. The National Dementia Strategy 2017-2020 (Scottish Government, 2017) highlights the need for development of staff competence and capability in order to facilitate this. However, there is little reference to the particular psychological factors required from these staff to develop their care of people with dementia. The Promoting Excellence Framework (Scottish Government, 2011)makes indirect mention of the good relationships required between staff and patients but does not explore the particular challenges which staff can face when working in dementia care environments. Therefore, while there is undoubtedly a move in policy towards recognising staff as one of the essential factors in the efficacy of dementia care, there are significant gaps in our understanding of the psychology of the staff needed to implement this.

Those working to care for people with dementia face similar challenges to other workforces. Workplace stress poses a significant problem in the UK workforce. In 2016/17, 12.5 million work days were lost due to workplace stress, depression and anxiety (Health and Safety Executive, 2017). One of the significant impacts of workplace stress on the individual is burnout. Burnout is recognised as a psychological experience related to emotional stress and strain at work. It was conceptualised by Maslach and Jackson and defined as being characterised by three dimensions: emotional exhaustion, depersonalization and reduced personal accomplishment (Maslach & Jackson, 1981). Healthcare workers are among those most at risk of burnout (Health and Safety Executive, 2017; Maslach, 2003) while nursing staff have been identified to exhibit even greater burnout than other healthcare professionals (Chou et al., 2014). However, the prevalence of burnout among nursing staff in dementia care settings is difficult to quantify, with a poor quality literature base providing estimates ranging from 5% to 53% (Kimura et al., 2011; Pitfield et al., 2011) across a variety of care settings. Staff burnout has been reported to be associated with poorer patient care, including reduced willingness to help; low optimism; negative emotional responses; poorer relationships with patients and carers; increased staff sickness rates and high staff turnover (Mackenzie & Peragine, 2003; Todd & Watts, 2005). Several contributing factors are believed to impact an individual's risk of burnout, including their sense of self-efficacy / self-competence and reciprocity in staff-patient relationships (Alidosti et al., 2016; Duffy et al., 2009; Mackenzie & Peragine, 2003). There is, however, a lack of acknowledgement in the literature that these factors are more likely to be present in dementia care settings and the impact this can have on staff wellbeing, and ultimately, patient care. Little attention has been paid to the particular psychological challenges faced by staff working in dementia healthcare settings, the impact this has on patients, or how these may be addressed.

Self-efficacy evolved from Bandura's social learning theory as the belief in oneself to accomplish specific goals (Bandura 1978). Bandura further asserts the most significant contributing factor in our emotions and behaviour is our belief in our ability to cope with a given situation (Bandura, 1997). Research has suggested high staff self-efficacy leads to a more positive experience of providing care for patients with dementia, better mood and better coping (Duffy et al., 2009; Semiatin & O'Connor, 2012). However, there is little consideration for the increased difficulty in establishing self-efficacy in dementia care setting

due to the progressive and degenerative nature of the disease. This is something which is not afforded significant consideration when intervention to improve staff self-efficacy among staff working in dementia care, which have been shown to facilitate short-term improvements in burnout; however, these are not maintained in the longer term (Awa, Plaumann, & Walter, 2010; Mackenzie & Peragine, 2003). This suggests a long-term intervention which increases staff self-efficacy over a sustained period would be necessary to reduce burnout effectively, however, there is little evidence of such interventions in the literature. The terms 'sense of competence' and self-efficacy' are used interchangeably in the literature. This proposal shall use the term sense of competence to encompass both terms.

A further factor of burnout which is particularly pertinent to dementia is the nature of the relationship between staff and patients. A lack of reciprocity in this relationship can be found in situations where the care professional feels they invest more in energy in the relationship with clients than is invested by the recipient of care (Duffy et al., 2009). The concept of reciprocity evolved from social exchange theory and was developed to the dual-level social exchange model of burnout (Schaufeli et al., 1996). It proposes the level of reciprocity mediates burnout in both interpersonal and organisational relationships (Bakker et al., 2000). The literature reports a societal perception that people with dementia, particularly those with advanced dementia, lack reciprocity (Gove et al., 2017). This is relevant in dementia care settings, as the instance of poorer cognitive abilities, challenging behaviour and decreased social ability may be detrimental to the staff's relationships with those they care for. However, there is little evidence of consideration of this in the literature and the small evidence base in this area provides only a tenuous link between relationships and burnout in dementia care (Duffy et al., 2009). This is at odds with evidence reported in other care populations and warrants significant further study, particularly as it has been suggested increasing reciprocity may serve to increase dignity and quality of life in patients. (Vernooij-Dassen et al., 2011). It remains to be seen whether interventions which help build relationships in dementia care can mediate staff burnout, and ultimately result in better patient care.

One of the factors which staff burnout is known to impact significantly is the provision of recreational activities for patients with dementia. There is a recognised need for high quality, accessible recreation opportunities for people with dementia (Buettner & Fitzsimmons, 2011; Kolanowski et al., 2009). However, increased emotional exhaustion caused by staff burnout can result in them facilitating fewer recreational activities for those in their care (Pulsford, 1997). Conversely, increasing recreational activities for people with dementia may act to reduce staff burnout while further improving outcomes for patients. Van Weert et al. (2005) demonstrated significant treatment effects in measures of staff sense of self-competence and emotional exhaustion following the introduction of Snoezelen therapy in nursing homes. It may be that providing staff with activities which they can facilitate with those with severe dementia allows them an increased sense of efficacy in that they can facilitate enjoyment and pleasure, even for those with advanced dementia. There is, however, little study of this concept to date, given the potential benefit both patients and staff, it would seem logical for this method of improving patient care to be further examined.

More broadly, interventions which focussed on the whole social environment (e.g. increasing patient centred care or co-operative communication in the care setting) are more effective in reducing staff burnout than those which solely focussed on staff (e.g. education programs) (Awa et al., 2010; Westermann., 2014). This poses the question of whether other accessible recreational activities for people with dementia may be beneficial for staff wellbeing, as well as that of the patient.

There are some psychosocial interventions for those with advanced dementia, such as Snoezelen therapy (Van Weert et al., 2005), the Veder 'theatre' contact method (Boersma et

al., 2017) and doll therapy (Cantarella et al., 2018). These methods often, however, require significant time investment from staff in the form of planning or training, which can discourage staff from using them or serve to increase their levels of stress. While technology-based recreational activities may offer a less staff-intensive option, there is a lack of evidence of the use of appropriate recreational activities using technology for those with advanced dementia (Anderiesen, 2017) and of their use in hospital settings.

There may, however, be a risk of new recreational activities introduced to care environments increasing the workload of staff. As increased workload is the greatest self-reported cause of workplace stress (Health and Safety Executive, 2017), a labour-intensive recreational activity poses the risk of further increasing staff burnout. Perhaps due in part to these concerns, there has been an increase in the use of technology to provide recreational activities for those with dementia while placing little additional pressure on staff (Dove & Astell, 2017). A recent systematic review reported 14 studies which suggested positive outcomes of touchscreen-technology use by people with dementia, both for themselves and their caregivers (Tyack & Camic, 2017). Qualitative data on the use of iPads in dementia care settings found staff reported it facilitated improved, more reciprocal relationships with those they were caring for (Swan et al., 2018) However, it has also been noted that some people with dementia, particularly those in the later stages of the disease, can struggle to operate this technology (Groenewoud et al., 2014). The potential of commercially available motion-based technology (such as the Nintendo Wii or X-box Kinect games consoles) (Dove & Astell, 2017) and virtual reality technology (Colombo et al., 2012) to provide recreational activities for people with dementia has also been highlighted in the literature. While these activities are reported to have many positive effects for people with dementia and to require little specialist input from staff, they can often prove inaccessible to those with more pronounced cognitive or physical impairments (Higgins et al., 2010). There is also little consideration given to the impact of these technological additions on staff. Do they add to staff workloads or do they ultimately help to reduce it? Can these technologically driven activities work on a deeper level of the staff/ patient relationship? There are many unanswered questions in this relatively new field of technologically driven recreation in dementia, particularly for those with severe dementia. Ultimately, if we are to move towards more technologically facilitated dementia care, we must be confident that we can do so in such a way that staff-patient interactions are enhanced, not neglected or replace. The current literature does not provide significant solutions to allow us this confidence, therefore we may need to look beyond existing commercial technology to find a solution which proves beneficial to both the patient and staff experience.

Objectives and Rationale of the Study

While the small number of studies to date suggests positive benefits for patients, there is little evidence of the impact the use of recreational technology, such as iPads or video games has on patients or staff in hospital settings. It may be that some technologically-driven recreational activities could help to reduce staff burnout by increasing reciprocity in staff/patient relationships and increasing staff sense of competence. They may, however, also be detrimental due to increased workload. Furthermore, the majority of research to date has focused on technological interventions tailored to those with mild to moderate dementia. Hence, it is important to investigate whether the impact of technologically-driven recreational activities on staff is a positive one, particularly those caring for individuals with advanced stages of dementia, who are more likely to be in acute dementia care hospital wards. These significant gaps in the literature require to be examined before significant funding is provided to these interventions.

The proposed study aims to carry out an evaluation of the impact on staff burnout of the introduction of the Tovertafel (Magic Table) (see intervention section 3.4 for a full description), on an acute dementia care hospital ward.

Methods

3.1 Design

A mixed-methods, ABC multiple-baseline single-case experimental study across-subjects will be employed. Phase A (multiple baselines), Phase B (Intervention) and Phase C (follow-up) will be utilised to analyse the individual effect on staff variables. In addition, a survey questionnaire will be collected from staff members on their thoughts and views at the end of the intervention.

Research Questions

What is the individual effect on staff burnout after the intervention?

What is the individual effect on staff perception of reciprocity after the intervention?

What is the individual effect on staff sense of competence after the intervention?

What is the individual effect between staff rated wellbeing at work and the use of the Tovertafel on the hospital ward?

3.1.1 Quantitative Arm

Utilising multiple-baseline single-case methodology allows for more precise delineation of any causal effects of the intervention, as participants act as their own control, allowing for inferences regarding the impact of the intervention on the individual to be determined (Blampied, 1999; Rizvi & Nock, 2008; Yin, 2009). This acts as an essential exploratory stage of an intervention before examinations of comparative group data by providing vital insights at a single case level. At the beginning of Phase-A, staff will work with the research team to select items from the measures of burnout, reciprocity and sense of competence to generate a set of bespoke outcome measures for each participant. This will include 1-2 items from each scale to a total of 4-6 items. This set of outcome measures will then be administered to that participant for the duration of the study. For Phase A, the bespoke outcome measures will be administered to participants across three staggered baselines, which will vary in length from 3 to 5 days (as Lanovaz et al., (2017) recommend each baseline have a minimum of three data points). Three baselines were deemed sufficient, as per the guidelines set out by Horner et al. (2005). This phase allows the establishment of stable baselines before the introduction of the intervention. Phase-B will comprise 12 weeks use of the Tovertafel on the hospital ward. Twelve weeks was felt to be an appropriate length of intervention, as this far exceeds guidelines of five data points (Lanovaz et al., 2017) and a similar intervention period has been used in a previous dementia intervention study (Guzmán et al., 2016). During this phase, participants will complete their bespoke set of measures once per week. Phase-C will comprise a 6-week naturalistic observation of the participants, completing bespoke measures once every two weeks.

During Phases A, B and C, staff will also complete a daily, single item measure of well-being to complement the primary measures in the multiple-baseline single-case analysis.

3.1.2 Qualitative Arm

At the end of Phase-B, staff will complete a short quantitative questionnaire detailing their experience with the Tovertafel which will provide qualitative data on staff experiences of the intervention.

3.2 Setting, Participants and Recruitment

The study will take place in the older adult dementia care ward, Cree, at Midpark Hospital, NHS Dumfries and Galloway. Cree is an acute ward which provides short to medium term care for patients with advanced dementia. The ward has sought to increase their use of technology and has already secured funding to introduce the Tovertafel.
A minimum of ten staff members will be recruited from those nurses and Health Care Assistants (HCAs) who regularly work on Cree ward. Posters and information leaflets will be distributed within staff areas in the ward to inform potential participants of the study. The principal investigator shall also attend team meetings on the ward to raise awareness of the project and answer any questions staff may have about participation A senior member of ward staff will be identified to act as staff liaison to further support the project. Approval for staff participation has been gained from senior managers within the hospital.

Inclusion Criteria

Registered nurses (any grade) and Health Care Assistants (HCAs) who routinely work exclusively on Cree ward.

Able to read and speak English fluently

Able to commit to the project for 24 weeks

Aged over 16 years of age

Exclusion criteria

Temporary staff expected to be on the ward for less than 24 weeks.

Senior nurse managers who do not routinely work on the ward

Nursing students on placement within the ward (due to them not being fully integrated into the culture on the ward.)

Staff who do not routinely work on Cree Ward (i.e. temporary cover from other wards)

Members of staff who visit the ward but do not solely work there (e.g. medical staff/psychologists/ allied health professionals)

3.2.1 Sample size

No definitive guidelines have been established on sample size in multiple-baseline single-case study designs. They may involve only one participant; however, Horner et al. (2005) suggest most studies typically carry out analysis on three to eight participants. Previous multiple baseline studies in dementia care have utilised three (Lancioni et al., 2015) and ten (Guzmán et al., 2016) participants. Therefore, ten participants will be an appropriate staff sample size for this study. Previous qualitative studies investigating aspects of burnout in

nursing staff have utilised similar sample sizes (Berg et al., 2016; Billeter-Koponen & Freden, 2005), as has an evaluation of dementia care environment (Morgan & Stewart, 1997).

3.2.2 Confidence in recruitment strategy

NHS senior managers in Dumfries and Galloway are supportive of research being carried out on the ward and will encourage staff to participate. The principal investigator (PI) will have regular access to hospital ward staff and carry out regular visits to encourage participation. Staff will be briefed that the research seeks to represent their experiences it is hoped staff will be interested in engaging with this project as a way of sharing their views of their workplace. To further encourage compliance with the regular data collection within the busy ward environment, staff will be offered the incentive of inclusion in a prize draw to win a £40 gift voucher to a retailer of their choice if they complete 90% or more of the required questionnaires.

3.3 Outcome Measures

3.3.1 Quantitative Arm – Outcome measures for Individual target behaviours

The outcome measures used in the study are outlined below. As described above in section 3.1.1, staff and researchers will jointly select Items from the burnout, reciprocity and sense of competence measures to generate a bespoke outcome measures for each staff participant. This bespoke outcome measure will be completed at baseline and weekly thereafter by staff and is estimated to take no more than 10 minutes to complete. The daily token measure is estimated to take no more than 30 seconds to complete.

Staff demographic information questionnaire

Staff will be required to provide demographic information in the form of a short questionnaire, adapted from Duffy et al., (2009). This will collect data on the participant's age; gender; job title; length of service within the NHS and in their current role; the number of hours usually worked in a week; their perceptions of the level of challenging behaviour they experience in their role and their home-life situation.

Abbreviated Maslach Burnout Inventory (aMBI)

The Maslach Burnout Inventory (MBI) (Maslach et al., 1996), is regarded as the 'gold standard' measure of burnout and comprises three subscales: emotional exhaustion (EE), depersonalization (DP), and personal achievement (PA). Higher scores on emotional exhaustion and depersonalisation and lower scores of personal achievements result in higher scores of burnout. The MBI is reported to have good validity and reliability in both clinical and non-clinical populations (Enzmann et al., 1995; Schaufeli et al., 2001). An abbreviated, 9 item version of the scale has been developed and utilised within healthcare settings (McManus et al., 2002). The abbreviated Maslach Burnout Inventory (aMBI) maintains the original three subscales, each of which has been found to have good internal reliability (α=0.83-0.88). Strong correlations are reported between the full subscales and their abbreviated counterparts (r=0.83-0.85) while the aMBI also reports good sensitivity (86.67–99.04%) and specificity (79.35–97.42%) in discriminating highly burned-out individuals (Riley et al.,2018).

Sense of Competence in Dementia Care Staff (SCIDS) Scale

The Sense of Competence in Dementia Care Staff (SCIDS) Scale (Schepers et al., 2012), provides a measure of staff's feelings of competence in their role. Respondents indicate how well they feel they can accomplish different aspects of dementia care across 17 items, on a four-point scale. The scale is composed of four subscales: professionalism; building relationships; care challenges; and sustaining personhood. Schepers et al., (2012) reported acceptable internal consistency on two of the subscales: "Care Challenges" (α=0.78) and "Sustaining Personhood" (α=0.70). Good internal consistency was reported for "Professionalism" (α=0.82) and "Building Relationships" (α=0.83) subscales, and for the full scale (α=0.91). Acceptable test-retest reliability is also reported.

Jeffcott Reciprocity Questionnaire

Van Horn et al., (2001) developed measures of reciprocity in work relationships in an education setting which have been adapted for use in healthcare settings. The Jeffcott Reciprocity Questionnaire *(*Jeffcott, 2002) was utilised in children's healthcare settings, but has subsequently been adapted by Duffy et al. (2009) for use in populations of staff providing care in dementia. The self-report questionnaire consists of 23 items across three subscales of perceived reciprocity between staff and their patients, colleagues and organisation, which are rated on a five-point Likert scale. This adapted scale has demonstrated alpha coefficients which ranged from 0.72 to 0.93 (Duffy et al., 2009). Only the staff-patient reciprocity subscale, which consists of three investment (α=0.72) and three outcome (α=0.82) items will be utilised in this study to provide a measure of the perceived reciprocity in the relationships between staff and their patients.

Daily measure of staff wellbeing

In order to provide a daily measure of staff wellbeing unobtrusively, a token collection system shall be in place on the ward. Staff will be allocated tokens marked with their participant ID number and will be asked to answer the question: "Thinking about your whole shift, how have you felt at work today?" at the end of each shift by 'voting' with their tokens. Staff will answer on a five-point scale by selecting a token of the colour which corresponds to their answer –"Great"; "Good"; "OK" "Not good"; "Awful". The tokens will be placed in opaque boxes (to protect confidentiality), one designated to each day of the week. The boxes shall be emptied weekly by the principal investigator and the tokens tallied against participant ID. Although this is a non-standardised measure, it provides a creative method of collecting data from participants on a daily basis without disrupting the busy hospital ward. There is president for single item measures being utilised to collect data on well-being, life satisfaction and happiness (Abdel-Khalek, 2006; Cheung & Lucas, 2014; Tabor & Stockley, 2018).

Staff sickness, Staff turnover and Adverse events

Non-standardised logs will be used to collect information on staff sickness and turnover rates as well as the number of adverse events reported on the ward during Phase-B.

3.3.2 Qualitative Arm

Staff Qualitative Questionnaire

Staff members will also complete a short quantitative questionnaire at the end of Phase-B which will inquire about their experience with the Tovertafel. As there is no current research on which to basis this questionnaire, it will be developed to answer the questions posed in this study. Questions will include:

What have you noticed about patients' moods and their engagement with activities in the last three months?

What have you noticed about your relationships with patients in the last three months?

What have you noticed about how you carry out your work duties in the last three months?

What have you noticed about how you feel about your work in the last three months?

What have you noticed about your stress levels while at work in the last three months?

What have you noticed about your satisfaction with work in the last three months?

3.4 Intervention

The Tovertafel utilises a projector which is mounted above a normal table in a communal area of the ward. It projects images on to the table below and utilises infra-red technology to detect the position of individual's hands in relation to the projected images. Participants can engage with the objects projected on to the table. The Tovertafel comes programmed with many games designed explicitly for people with a diagnosis of advanced dementia, which are played by interacting with the projected images.

The Tovertafel (meaning Magic Table in Dutch), a digital projection and infra-red detection device, was developed in the Netherlands (https://tovertafel.com). It was designed to provide an interactive and playful recreation activity for people with moderate to severe dementia (Anderiesen, 2017). The Tovertafel projects light on to a table below and can detect user's movements, allowing them to interact with many specially designed games. One published study of the Tovertafel has examined the quality of life in nursing home residents who used the device. It reported residents demonstrated a small to moderate improvement in 'negative affect', 'restless tense behavior'(sic) and 'positive self-image' up to one week after using the table (Bruil et al., 2017). To date, there has been no analysis of the impact of the Tovertafel on staff, but given the emphasis on collaborative engagement between the patients and care staff when using the device, it seems plausible there could be an impact on reciprocity and sense of competence. This proposed study is timely and follows an increasing focus from both professional bodies and the Scottish Government to increase the use of technology in nursing care, reduce staff burnout and foster better staff/ patient relationships in older adult hospital settings (Healthier Scotland, 2017; Ross & Dexter-Smith, 2017).

Delivery

It is operated by staff using a remote control and is designed to be quick and easy to set up in busy care environments. In Phase-A, the Tovertafel will not be used on the ward. In Phase B & C, staff on the ward will use their clinical judgement to determine the frequency and duration of the use of the Tovertafel over the 12-week period.

Material

The Tovertafel device has been purchased by NHS Dumfries and Galloway and will be sited on Cree ward before the commencement of the study. The Tovertafel is supplied with pre-installed games specifically designed for use by those with moderate to severe dementia.

Increasing adherence and fidelity

The frequency, duration and a brief descriptive summary of each use of the table will be logged by ward staff. In order to avoid any contamination of the intervention, the principal investigator will not be involved in the use of the Tovertafel on the ward at any time during the study. As this study will examine the use of the Tovertafel in a natural hospital environment, the degree of use of the Tovertafel will not be strictly specified. Throughout the study, however, ward staff will be supported and encouraged to use the Tovertafel at least twice per week by the specialist dementia intervention team.

3.5 Procedure

See Figure 1. for a summary of the proposed procedure.

Staff who have demonstrated an interest in the project will be provided with further information on the requirements of the study, and their written, informed consent to participate will be sought. Once participants have been recruited, participants will meet with the research team to complete the demographic questionnaire and to carry out the item-selection procedure outlined in sections 3.1.1 and 3.3.1.

Participants will then be randomised to one of the three baselines (3 days, 4 days or 5 days) by a researcher external to the project. Randomisation will be carried out using a random number generator to allocate participants to one of the three baselines.

Baselines shall be completed on ‘working days’ only, as the study is concerned with experiences at work. Participant’s working shift pattern shall be analysed to determine when each participant's baseline should start. For example, if a participant is allocated to the 5-day baseline but is only scheduled to work three days in week one, then their 5-day baseline would be completed over the three days in week one and their next two working days in week two.

Participants will be provided with the dates on which they will be required to complete measures and instructions for completion. Copies of the burnout, reciprocity and self-competence measures will be made available in a staff area of the ward. Staff will be assigned a unique participant ID number and provided with envelopes marked with their ID number to facilitate the confidential return of the measures. Completed measures will be sealed in the envelope and placed in a tamper-evident box within the staff area.

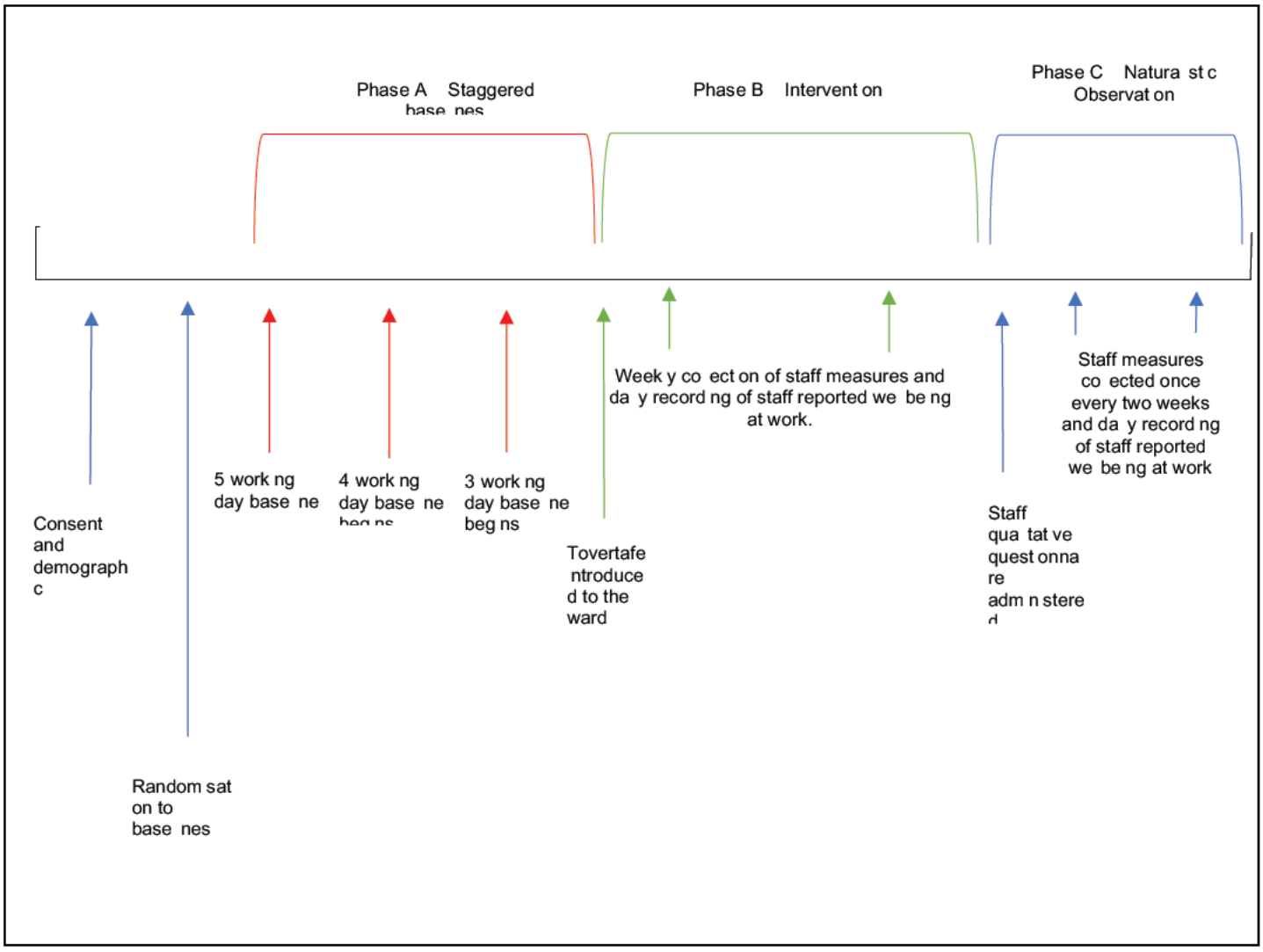
In Phase-A, staff participants will be required to complete the bespoke measures once per day for their specified baseline duration (e.g. 3,4 or 5 working days). These measures will be distributed and collected as described above. The principal investigator shall attend the ward regularly during the baseline phase to monitor and encourage compliance and to collect completed measures. This will allow for a stable baseline of staff measures to be established before the intervention.

Following the completion of Phase-A, the Tovertafel will be introduced to the ward. Phase-B will last for 12 weeks, during which time, participants will complete the bespoke burnout, reciprocity and self-competence measures once per week. In Phase-C, a 6-week naturalistic observation will be carried out on the ward, and staff will complete the outcome measures once every two weeks. During Phases B & C, completed measures will be returned as described above. The Tovertafel will not be withdrawn from the ward during this stage. The frequency and duration of the use of the Tovertafel during this period shall be logged during Phase B & C.

To encourage compliance with the regular data collection within the busy ward environment, staff shall be offered the incentive of inclusion in a prize draw to win a £40 gift voucher to a retailer of their choice if they complete 90% or more of the required questionnaires.

As a daily measure of staff wellbeing during Phase-B, staff will indicate how they felt about their day at work at the end of each shift. This will be achieved by staff placing a token corresponding to their response to a daily well-being question into a box allocated to that day. This measure, alongside the qualitative measures described below, complement the primary multiple baseline single case study methodology.

Figure One – Summary of the study procedure



3.6 Statistical analysis

3.6.1 Quantitative Arm

Demographic data

The demographic data collected will be examined using descriptive statistics.

Multiple Baseline Analysis - n=10 Case studies

Participants' questionnaire scores for their bespoke questionnaire items will be plotted and a visual analysis of trend and difference between phases of the experiment considered. The statistical analysis of the trends between baseline (Phase A) and the intervention (Phase B) shall be conducted using a 'percentage of all non-overlapping data' (PAND) analysis shall be carried out on data from staff individual measures and token system. PAND examines the number of observations from baseline overlapping with observations in the intervention phase (Parker et al., 2007). PAND allows for an analysis of difference in an individual's scores between the different phases of the study, allowing for conclusions to be drawn about any impact of the intervention at a single-case level. This can then be aggregated with data from all participants to provide information on the intervention's impact on this group of single case studies. This will provide preliminary data on the impact of the Tovertafel on staff. The steps of the PAND analysis are outlined in Table One , below.

Table One – Summary of Multiple-Baseline Single -Case Study PAND statistical analysis.

Step	Procedure
1	Data from each of the three staff outcome measures (aMBI, reciprocity and SCIDS questionnaires and well-being measure) graphed across phases to allow for visual inspection. Identify non-overlapping cut-off score.
2	Assess the number of overlapping data clusters for each participant - i.e. the "minimum number [of data points] that would have to be swapped across phases for complete score separation" (Parker et al., 2007, p197).
3	Calculate PAND. PAND is equal to remaining data, once all over overlapping data is excluded, divided by total data observations. PAND can then be rescaled to facilitate comparison as per Parker et al., (2011).
4	Calculate Phi and confidence intervals (C.I.s)– A 2x2 table is constructed with higher and lower scores of Phase-A and Phase-B for each outcome measure to obtain effect sizes for Phase-A vs Phase-B scores. Phi and C.I.s calculated using an online program from statspages.info (Pezzullo, 2010).
5	Interpret effect size using criteria defined by Parker et al., (2011), as Cohen's conventions do not fit single case research (Rosnow & Rosenthal, 1989).
6	Meta-analysis to aggregate effect size across all participants. Computed with WINPEPI program (Abramson, 2011) using Phi coefficients.

Non-standardised measures - staff absence, turnover, adverse incident and use of Tovertafel

Non-standardised measures will be analysed using correlational and descriptive analysis.

3.6.2 Qualitative Arm

The qualitative staff questionnaire will be analysed using thematic analysis by seeking out and summarising themes from the data, as per the process described by Braun & Clarke (2006). A Synthesised Member Check, as described by Birt et al., (2016) will seek to ensure themes accurately reflect the experiences of staff. The results of the thematic analysis will be used to identify themes regarding any change in the staff experience on the ward following the introduction of the Tovertafel.

3.7 Ethical considerations

As with any new intervention within an acute, dementia care setting, there is a risk the introduction of the Tovertafel may cause distress to some patients. This risk has been carefully considered and will be monitored throughout the study to ensure it is reduced as far as possible. The Tovertafel is a planned addition to the activities already on offer on the ward. Any distress will be managed in line with usual ward procedures by the highly experienced staff, who will utilise their clinical judgement to monitor and respond to signs of distress. Anecdotal evidence suggests the Tovertafel has been well received in other care settings, with highly positive reports from staff and patients (Rix, 2016). As the introduction will be part of treatment-as-usual on the ward, patients will be encouraged to engage with the Tovertafel, but will never be forced to do so and will be facilitated to disengage with it at any time should they show signs of distress.

The topics in the staff outcome measures may be emotive for some members of staff, and therefore careful consideration has been given to the management of any potential staff distress. Information sheets provided to staff participants will encourage them to speak with senior colleagues or supervisors if they have concerns about topics raised in the study. The principal investigator (PI) will be present on the ward regularly throughout data collection phases, and as a second and third-year trainee clinical psychologist has clinical experience in assessing and containing psychological distress. The staff liaison, a senior member of ward staff, will meet regularly with the PI to provide updates and highlight any areas of concern regarding staff interaction with the outcome measures. The PI will work in close contact with the project's clinical supervisor in the management of any staff distress and information regarding relevant support (such as occupational health services and professional supervision) will be made available to staff at all points of the study.

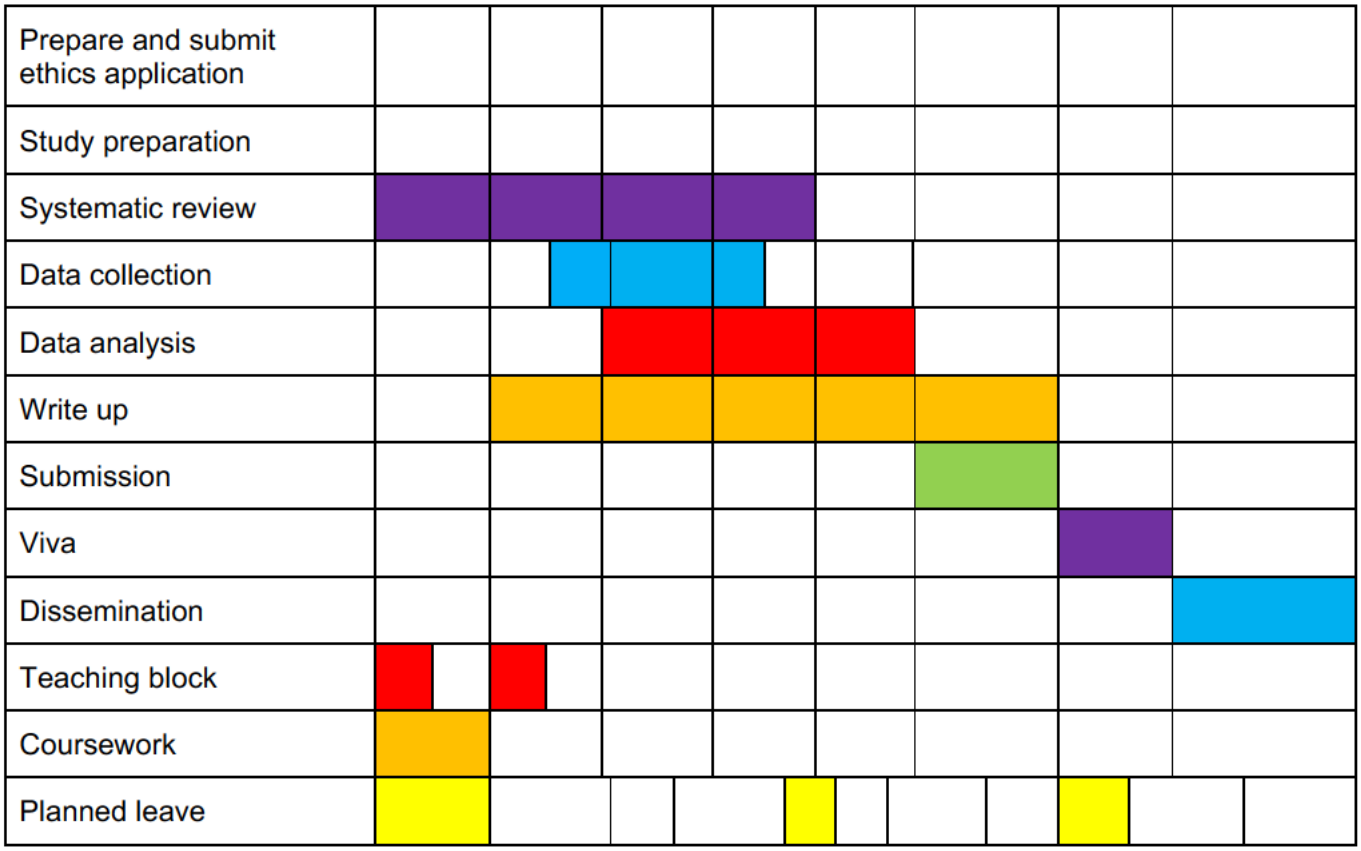
Ethical approval will be sought from NHS Dumfries and Galloway R&D department.

Project management

The proposed timeline for the project is outlined in Figure Two below.

Figure Two – Gantt chart of project management plan (revised)

	2019				**2020**			
	April - May	June – July	Aug - Sept	Oct – Nov	Dec - Jan	Feb - March	April - May	May - Onwards
Submit Proposal								



Risk management

The identified risks for the project and the steps taken to mitigate them are described in Table Two below.

Table Two - Table of Identified risks, perceived level of risk and steps to mediate risk

Risk identified	**Level of risk**	**Steps taken to mediate risk**
Risk the project will not receive R&D approval	Low	-Ethics submission will be developed with the assistance of both the academic and clinical supervisors, both of who have experience of taking research before university ethics committees and NHS R&D departments. -The academic supervisor has considerable experience of research in the field of dementia and will provide advice regarding the presentation of the study to the committee. -Treatment-as-usual nature of the study will be emphasised in ethics application, highlighting that the study will not be modifying the treatment or experience of patients in any way.

		-Additional time allowed in the timeline, for resubmission if necessary
Risk of either supervisor becoming unavailable	Low	-Both supervisors have expressed support for the project and their intention to work with it through to its completion. -If a supervisor becomes unavailable, the principal investigator will endeavour to arrange a replacement supervisor as quickly as possible. -Older adult psychology team within the health board are supportive of the project, therefore likely a replacement supervisor could be recruited without significant difficulty. -May be more difficult to recruit a new academic supervisor if this proved necessary, however, the principal investigator would seek to explore the available options with the University as soon as possible.
Risk of staff participants being under-recruited, unavailable or unwilling to complete multiple questionnaires	Low	-Significant support for the project from senior members of staff at various levels -Agreement to staff completing the questionnaires during working hours. -The small sample size required -Prize draw incentive to encourage staff compliance with multiple data collections

Potential benefits of the project

It is anticipated the findings of this study may have local, national and international applications.

In a local context, it is likely to provide senior managers with further insight into staff wellbeing and may inform future planning within the hospital. It is also hoped to generate positive publicity for the ward and the health board in the local press.

Nationally, the project will inform the application of the Tovertafel in the NHS. It may provide relevant evidence when health boards make decisions on funding for Tovertafels. It will also

provide an appraisal of the impact of introducing a new technology intervention on staff, which may inform future planning around the inclusion of technology as a support to staff.

Internationally, the study will add to the very small, but growing body of evidence on the Tovertafel, which may then lead to further development of other technological interventions for those with advanced dementia.

Dissemination

The project in its entirety will be submitted in partial fulfilment of the principal investigator's Doctorate in Clinical Psychology, and as such, the thesis will then be available through the Department of Clinical Psychology Thesis Database, providing open access to the results of the study.

The principal investigator will further seek to prepare the findings of both the systematic review and the empirical research for publication in a peer-reviewed academic journal. The principal investigator shall also seek opportunities to present the findings of the study at relevant academic conferences, such as the Alzheimer's Society Conference.

It is intended to present the findings of the findings of the study to stakeholders within NHS Dumfries and Galloway. The principal investigator will also endeavour to share the results of the study directly with the staff group from which the participants were recruited, either through a short, written summary or through a presentation at team meetings. There may be scope for publicising the findings of the research more widely through local media outlets, due to the innovative nature of the technology being used.

The principal investigator will also endeavour to consult with both the local patient experience group and the Scottish Dementia Working Group. Advice will be sought from them regarding other potential avenues for broader dissemination.

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Appendix– Definitions of Abbreviations used in Text

aMBI Abbreviated Maschlach Burnout Inventory

MBI Maschlach Burnout Inventory

PAND Percentage All Non-overlapping Data

PI Principle Investigator

SCIDS Sense of Competence In Dementia Scale

Appendix E – Empirical Study Participant Information Sheet and Consent Form

Participant Information Sheet and Consent Form

Staff

Impact of the Tovertafel (Magic Table) on staff burnout

You are being invited to consider giving your permission to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for reading this.

What is the purpose of the study?

The study aims to investigate the impact of introducing the Tovertafel to Cree Ward. The Tovertafel (which means Magic Table in Dutch) is an exciting addition to the activities already on offer on the ward. It allows patients and staff to interact with images projected on to a table to play simple, fun games together. It has been specially designed for people who have a diagnosis of dementia. This study will aim to understand the impact that the introduction of the Tovertafel has on staff burnout.

Why have I been chosen?

You have been asked to take part in the study because you are employed as a nurse, or Health Care Assistant (HCA) on Cree Ward at Midpark Hospital.

Do I have to take part?

No. It is up to you to decide whether you take part in the research or not. If you decide not to take part this will not affect your employment or work duties now or in the future.

If you decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. You are free to change your mind at any time and without giving a reason. Changing your mind about taking part will not affect your employment or work duties now or in the future.

What will happen to if I take part in the research?

If you decide to take part in the research you will be asked to compete a consent form, acknowledging that you wish to be part of the study. You will then be asked to complete a short questionnaire to provide information about your employment (e.g. what your job role is, how long you have worked in that role etc.). You will then be given a unique ID number to use throughout the study to allow your data to remain anonymous.

During the study, you will be asked to complete a few short questionnaires on a number of occasions, outlined below. These questionnaires will ask about how you feel carrying out your job and how well you feel you can carry it out.

Phase One

You will meet with a member of the research team and who will explain the study to you. They will ask you to complete a short questionnaire telling us about yourself (your role, how long you have worked for the NHS etc.). They will also ask you to look at a list of questions and select those which you feel apply most to you and your job. These will be the questions you will be asked throughout the study.

We will ask you to complete this short questionnaire once per day for 3,4 or 5 days in the initial part of the study. This will be before the Tovertafel is introduced to the ward. You will also be asked to briefly rate how you found each day at work after each shift, by voting with a token with your unique number on it. You will select a token which corresponds to your answer to the question "Thinking about your whole shift, how have you felt at work today?" and place it in the collection box.

Phase Two

Once the Tovertafel has been introduced to the ward, you will be asked to complete the same questionnaires you completed in phase one, once per week during your time at work. You will also be asked to continue to use the token voting system to rate how your shift has been. This will happen for 12 weeks.

Phase Three

In the final part of the study, you will be asked to complete a final, short questionnaire describing your experiences over the past 12 weeks. You will also be asked to complete the same questionnaires as in Phase One and Two once every 2 weeks for six more weeks, as well as continuing to rate how your shift has been.

You will be reminded by email from the research team when you need to complete these questionnaires.

How long will the research take?

The whole research project will last for approximately 4 months. During this time, you will be asked to complete questionnaires which take approximately 10 minutes to fill out. You will be asked to complete this once per day for 3-5 days initially, then once per week after that for 12 weeks, then once every two weeks for a six-week period. You will also be asked to briefly rate how you feel your shift has been on each occasion you work, which should take no more than 30 seconds each time.

What are the possible benefits of taking part?

You may or may not receive a direct benefit from taking part in this study.
Information gathered from this study may help to inform how interventions like the Tovertafel

are used in your ward and in other locations. It may also inform managers about the levels of staff burnout on your ward and how this can be improved. As the research is asking about how you feel while at work, this may also give you an opportunity to provide feedback to senior managers about your experiences of work.

Staff who participate in the study and complete 90% or more of the required questionnaires will also be entered in to a prize draw to win a £40 gift voucher to a retailer of their choice.

What are the possible disadvantages and risks of taking part?

Staff will be required to commit to completing questionnaires regularly throughout the study and providing an indication of how their working day was after every shift. There is a time commitment associated with this, although this has been kept to a minimum, with questionnaires taking no more than 10 minutes to complete and the rating of each shift taking only 30 seconds to complete.

There is a small risk that some staff may find the questions in the questionnaires upsetting to answer. If this is the case, help will be made available to you by the research team, who will direct you to appropriate sources of support, such as your line manager or occupational health department, and you can choose to discontinue with the study if you wish.

What if there is a problem?

If you have a question or concern about any aspect of this study please contact Fiona Beaton on: 01387 244495 or email: , who will do their best to answer your questions.

In the unlikely event that something goes wrong and you are harmed during the research and this is due to someone‘s negligence then you may have grounds for a legal action for compensation against NHS Dumfries and Galloway but you may have to pay your legal costs. The normal line management complaints mechanisms will still be available to you (if appropriate).

What happens when the study is finished?

The information you provide during the study will remain confidential and will be analysed to understand how the Tovertafel may or may not have affected how you feel at work. This anonymous data will then be stored securely for an initial period of 5 years, after which it will be reviewed to determine if it should continue to be securely stored. This retention of data allows us to ensure that the findings we report can be justified in the future if required.

Will taking part in the study be kept confidential?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard the privacy participants at every stage. Your answers will not be shared directly with your manager or other staff members, although we will provide managers and staff with a summary of findings from the study. Your answers will be kept anonymous and confidential through out every part of the study and in the future.

Your anonymised information will be stored securely within NHS Dumfries and Galloway and on University of Edinburgh servers

To ensure that the study is being run correctly, we will ask your consent for responsible representatives from the Sponsor, the University of Edinburgh and the NHS to access the data collected during the study, where it is relevant to them taking part in this research. The Sponsor is responsible for overall management of the study and providing insurance and indemnity.

What will happen to the results of the study?

The study will be written up as a doctoral thesis as part of the Doctorate in Clinical Psychology degree. It will also be written up for publication in an academic journal and, if appropriate, as a conference presentation. A short summary of the study will also be shared with staff and may be released to the press, to highlight the innovations taking place on the ward. You will not be identifiable in any published results and your answers will remain anonymous and confidential.

A summary of the results of the study will also be available to you on Cree Ward following to completion of the study. If you would like to a copy of this summary to be sent directly to you, please contact Fiona Beaton on the details below.

Who is organising the research and why?

This study has been organised by Fiona Beaton, a Trainee Clinical Psychologist with NHS Dumfries and Galloway and the University of Edinburgh. The project is supervised by Dr Azucena Guzman, University of Edinburgh and Dr Gillian Bowie, NHS Dumfries and Galloway.

Who has reviewed the study?

The study proposal has been reviewed by the University of Edinburgh Psychology research Panel. A favourable ethical opinion has been obtained from the University of Edinburgh, School of Health in Social Science. NHS management approval has also been obtained

If you have any further questions about the study please contact Fiona Beaton on: (01387 244495) or email:

If you would like to discuss this study with someone independent of the study please contact: Dr Angus Macbeth on 0131 650 3893

The Data Protection Officer can be contacted at the following email address: dpo@ed.ac.uk

If you wish to make a complaint about the study please contact : Matthias Schwannauer on 0131 651 3954. Further details on making a complaint can be found here: **http://www.ed.ac.uk/files/imports/fileManager/WEB Complaint Form.pdf**

Thank you for taking the time to read this information sheet

Staff Participant Consent Form

Impact of the Tovertafel (Magic Table) on staff burnout

Participant ID:

Please initial box

1. I confirm that I have read and understand the information sheet (*PISCF (Staff), version no.2 31/05/2019*) for the above study and have had the opportunity to consider the information and ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw from the study at any time, without giving any reason and without my employment or legal rights being affected. ☐

3. I understand that relevant sections of data collected during the study may be looked at by individuals from the regulatory authorities and from the Sponsor(s) (NHS Lothian and the University of Edinburgh) or from the/other NHS Board(s) where it is relevant to my taking part in this research. I give permission for those individuals to have access to my records. ☐

4. I agree to take part in the above study ☐

_____	_____	_____
Name of person giving consent	Date	Signature

_____	_____	_____
Name of person taking consent (if different from Researcher)	Date	Signature

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Appendix F – Empirical Study Demographic Questionnaire

Staff Initial Questionnaire **Participant ID number _____**

About your job

1) Your current job title: _____

2) Length of time in this organisation (NHS):_____
3) Length of time as an employee in your current work location (Cree Ward):_____

4) a) How many hours are you contracted to work each week?_____

b) How many hours did you actually work over the last full working week?_____

c) If more than your contracted hours, did you have any input in this decision? (Please circle)
Yes No

5) How challenging do you perceive the behaviour of the people you work with to be? (Please circle)
- Not challenging
- Slightly challenging
- Moderately challenging
- Very challenging
- Extremely challenging

About you

8) Age _____ years

9) Do you identify as: - Female
- Male
- Other

10) Are you: - Single
- Living with partner/married
- Separated/divorced
- Widowed

11) a) Do you have any dependant children living with you? Yes No

b) Do you have any other dependants living with you? Yes No

To make it easier for you to take part in the study, we can send you email reminders when you need to complete a questionnaire. If you would like us to send you reminders, please write your email address below. Your email address will not be linked to any of your answers in the study and will only be used to send reminders.

Email address

Appendix G – Shift by shift satisfaction measure

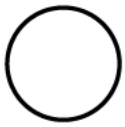
Daily measure of wellbeing at work

Please answer the question below at the end of your shift.

Chose the colour which best describes your day from the choices below.

Place a token of that colour with your participant number on it in today's box.

"Thinking about your whole shift, how have you felt at work today?"



- White – Great

- Yellow – Good

- Green – OK

- Blue – Not good

- Red - Awful

Appendix H – Empirical Study Qualitative Questionnaire

Staff Questionnaire

Participant ID number

Please answer the questions below as fully as possible. Please continue on another sheet if you require more space. When you have finished, please place your completed questionnaire in to the confidential box on the ward.

1. What have you noticed about patients' moods and their engagement with activities in the last three months?

2. What have you noticed about your relationships with patients in the last three months?

3. What have you noticed about how you carry out your work duties in the last three months?

4. What have you noticed about how you feel about your work in the last three months?

5. What have you noticed about your stress levels while at work in the last three months?

6. What have you noticed about your satisfaction with work in the last three months?

Thank you for completing this questionnaire and for your participation in the study. Your contribution is greatly appreciated

Appendix I – University Research Ethics Application and Approval

University of Edinburgh, School of Health in Social Science

RESEARCH ETHICS APPLICATION (REA)

The forms required when seeking ethical approval in the School of Health and Social Sciences have now been merged into this single electronic document. The sections you are required to complete will depend on the nature of your application. Please start to complete the form from the beginning and proceed as guided. **On completion the *entire* document should be submitted electronically to your section's ethics administrator using the email addresses detailed on the final page.**

Applications submitted without appropriate documentation will be returned.

	Sections of Forms		Summary of 'Methods'
Please indicate what sections of the SHSS Ethics forms completed herewith (✓):	**Level 1**	**Level 2/3**	

FORM OVERVIEW	
SECTION	**COMPLETION**
Project registration form	Compulsory for all applications
Document checklist	Compulsory for all applications
Level 1 Self Audit form	To be completed for all research studies that are not subject to review by an external UK based ethical committee.
Level 2/3 ethical review form	To be completed when indicated by responses on the Level 1 form

Confidentiality and Handling of Data	To be completed by all applicants using personal data[3] as part of their research
Security Sensitive Material	To be completed by all applicants completing the Level 2/3 ethical review form.
Risks to and safety of researchers named in this application	To be completed by all applicants completing the Level 2/3 ethical review form.
Risks to and safety of participants	To be completed by all applicants completing the Level 2/3 ethical review form.
Research Design	To be completed by all applicants completing the Level 2/3 ethical review form.
Bringing the University into disrepute	To be completed by all applicants answering 'yes' to question SA3.

PROJECT REGISTRATION FORM

This form is the first stage in applying for University ethical approval and should be completed prior to the commencement of any research project. Applications submitted without appropriate documentation will be returned.

[3] Personal data is "any information relating to an identifiable person who can be directly or indirectly identified in particular by reference to an identifier". This includes structured recorded information about a living individual, that is identifiable directly or indirectly including by online identifiers.

Ethical approval is required for all projects by staff or students conducting research, or similar.

Applicants should familiarise themselves with the School's Research Ethics Policy prior to completion.

PR1 Name of Applicant: Fiona Beaton
PR2 Name of Supervisor[4]**:** Azucena Guzman
PR3 Project Title: A mixed-method multiple-baseline single-case study exploring the impact of the Tovertafel (Magic Table) on staff burnout in an acute dementia care hospital ward.
PR4 Subject Area (section of school): Clinical and Health Psychology
PR5 If student, type of assessed work that this application relates to: DClinPsy Thesis
PR6 Planned date of project submission: March 2020
PR7 Date ethics application submitted: 24/06/19
PR8 (Date complete information submitted if different):
PR9 IRAS Approval Number if applicable:
The following to be completed by ethics administrator
PR10 ***Date of initial response to applicant:***
PR11 ***Date of final approval:***
PR12 ***Amendments Requested Date:***
PR13 ***Amendments Approved Date:***
PR14 ***Reviewer 1***
PR15 ***Reviewer 2*** ***Level 2/3 only***
DOCUMENTATION CHECKLIST

DC1 Does your research project require extraction or collection of data abroad? (✓)

✓	**No**	*If 'No' Skip to DC2*

[4] Not applicable to staff members.

	Yes	Local Ethical review needed, please confirm (✓) you have included an electronic attachment of: *application to ethical review panel in country of data collection (in English)* **+** *copy of letter of approval*

DC2 For the purposes of this research study, will you access identifiable[5] information on any NHS patient? (✓)

✓	**No**	*If 'No' Skip to DC3*
	Yes	Please confirm (✓) you have included an electronic attachment of: ***Caldicott Guardian*** *approval for use of NHS data or confirmation that it is not required*

DC3 Does the project require ethical review by an external UK committee e.g. NHS REC or Social Work?

✓	**No**	*If 'No' Skip to DC4*
	Yes	Please confirm (✓) you have included an electronic attachment of: *NHS REC (IRAS) /other application form* **+** *copy of letter of approval*

NOTE: If you have answered 'yes' you are ***not*** required to complete University ethical review forms. **Skip to DC6.**

DC4 Unless you answered 'yes' to DC3, you must also obtain ethical approval through the University of Edinburgh process. Please complete and submit the rest of this form (with 'Methods' summary).

DC5 Please list any additional documentation provided in support of your application (E.g. Disclosure, consent form, participant information, GP letters etc., Data Storage Plan)

Documentation Name **These should reflect content**	(✓)	**Documentation Name**	(✓)
Study Protocol		Staff Recruitment Poster	
Participant Information and Consent Form		Staff Sources of support information sheet	
Outcome Measures		Staff Qualitative questionnaire	

[5] 'Identifiable information' refers to information that would allow you to know, or be able to deduce, the identity of a patient. The most common examples of this would be accessing medical records or similar, or accessing a database that includes patients' names.

Staff Demographic Questionnaire		Staff Sources of Support Information sheet	
Daily measure of wellbeing		Data Protection Information sheet	

DC6 Signatures

____Fiona Beaton ____ _____ _____ __17/06/2019_____

Applicant's Name Applicant's Signature Date signed

___Azucena Guzman_____ _____ _____ _____ 19/06/2019_____

Supervisor[6] Name Supervisor's Signature Date signed

Please return an electronic copy of your UoE HSS Ethics Application Form (in its entirety) to your Subject Area Ethics Administrator, accompanied by electronic copies of additional documents indicated above. We do not accept paper documentation; please scan all documents into electronic formats. Please keep a copy of all documentation for your records.

SELF AUDIT FORM: LEVEL 1

The audit is to be conducted by all staff and students conducting any type of empirical investigation, including research, audit or service evaluation.

The form should be completed by the principal investigator and, with the exception of staff, signed by a University supervisor.

[6] Not required for staff applications.

SA1 Primary Research Question:

Please tick	What type of research are you planning to do?
	Study of a novel intervention or randomised clinical trial to compare interventions in clinical practice
✓	Study utilising questionnaires, interviews or measures, including auto-ethnographic data.
	Study limited to working with routinely collected clinical data.
	Meta-analysis or systematic review.
	Research database containing non-identifiable information.

SA2 Please provide a brief summary of your proposed study. Our interest is in areas of your methodology where ethical issues may arise so please focus your detail on areas such as recruitment, consent, describing your participants and the nature of their involvement, and data handling.

Background

Research has suggested recreational activities benefiting patients with dementia may also help to decrease staff burnout by increasing staff sense of competence and improving staff/patient relationships. This study will evaluate a new technological recreation activity for patients in a dementia-care hospital ward. The Tovertafel ('Magic Table' in Dutch), projects light on to a table below and detects user's movements, allowing them to interact with specially designed games.

The study will recruit staff from an NHS dementia care ward in Dumfries & Galloway. It will last for 20 weeks, using regular questionnaires to measure staff burnout, staff-patient reciprocity, staff sense of competence and well-being. Staff members will complete bespoke questionnaires before and during the time the Tovertafel is used on the ward. After the Tovertafel has been used on the ward for 12 weeks, staff will complete a further questionnaire asking them to describe any changes they have noticed since the introduction of the Tovertafel, followed by a follow-up questionnaire period of 6 weeks.

Recruitment

A minimum of ten staff members from the dementia care ward will be recruited from those

nurses and Health Care Assistants (HCAs) who regularly work on that ward. Posters and information leaflets will be distributed within staff areas in the ward to inform potential participants of the study. The principal investigator shall also attend team meetings on the ward to raise awareness of the project and answer any questions staff may have about participation. A senior member of ward staff will be identified to act as staff liaison to further support the project. Approval for staff participation has been gained from senior managers within the hospital.

Consent

All potential participants will be provided with an information sheet which describes their involvement in the study and how the collected data will be used. Staff will be given at least 24 hours to consider their participation in the study and ask any questions they may have of the research team. If they are happy to proceed as a participant, they will complete a written consent form, which will be retained for the duration of the study.

Methodology

Participants will be assigned an ID number to allow their responses to be recorded without directly identifying them. A member of the research team will meet with each participant to help them select appropriate bespoke outcome measure items for the sense of competence, reciprocity and burnout measures which are felt to be most applicable to them. This will include 1-2 items from each scale to a total of 4-6 items and will establish the bespoke questionnaire that each participant will complete throughout the study. Participants will also complete a short demographic questionnaire and then be randomised to a baseline of three, four or five days.

During Phase A, staff members will complete their short, bespoke questionnaires for three, four or five working days, depending on the baseline to which they have randomised. At this time, staff will also begin to record their evaluation of their own wellbeing following each of their work shifts. This will be facilitated by staff members placing a token corresponding to their answer on a five-point square into an opaque box at the end of their shift.

Following the completion of the baseline measures, Phase B will begin and the Tovertafel system will be introduced to the ward. Staff will encourage patients to engage with the Tovertafel and will facilitate sessions with the Tovertafel for patients, recording how frequently it is used. This intervention period will last for 12 weeks. During this phase, staff will continue to complete their bespoke questionnaire items and daily token measure of self-rated wellbeing (as above) on a weekly and daily basis respectively.

After 12 weeks, the intervention period will end. Staff will be requested to complete a short qualitative questionnaire at this time point, detailing their experiences of using the Tovertafel with patients. Phase C will last for six weeks, consisting of a naturalistic follow-up phase where staff will continue to track their wellbeing daily and to complete their bespoke questionnaires once every two weeks.

Following the completion of phase C, those staff who have completed 90% or more of the required questionnaires, will be entered into a draw, with the winner receiving a £40 gift voucher to the retailer of their choice. Following the analysis of the qualitative data, staff

participants will be given the opportunity to take part in a synthesised member check, whereby they can provide feedback to the research team on the interpretation of their qualitative data.

Data Management

Dissemination

The project in its entirety will be submitted in partial fulfilment of the principal investigator's Doctorate in Clinical Psychology, and as such, the thesis will then be available through the Department of Clinical Psychology Thesis Database, providing open access to the results of the study. The principal investigator will further seek to prepare the findings for publication in a peer-reviewed academic journal. It is also intended to present the findings of the findings of the study to stakeholders within NHS Dumfries and Galloway. The principal investigator will also endeavour to share the results of the study directly with the staff group from which the participants were recruited, either through a short, written summary or through a presentation at team meetings. There may be scope for publicising the findings of the research more widely through local media outlets, due to the innovative nature of the technology being used.

Identified ethical Issues

The topics in the outcome measures may be emotive for some members of staff, and therefore careful consideration has been given to the management of any potential staff distress. While this is assessed to be a minimal risk, steps have been taken to support staff with any psychological difficulties they experience as a result of the study. Information sheets provided to staff participants will encourage them to speak with senior colleagues or supervisors if they have concerns about topics raised in the study. The principal investigator (PI) will be present on the ward regularly throughout data collection phases, and as a second and third-year trainee clinical psychologist, has clinical experience in assessing and containing psychological distress. The staff liaison, a senior member of ward staff, will meet regularly with the PI to provide updates and highlight any areas of concern regarding staff interaction with the outcome measures. The PI will work in close contact with the project's clinical supervisor in the management of any staff distress and information regarding relevant support (such as occupational health services and professional supervision) will be made available to staff at all points of the study.

There is also a potential issue of the burden regular and repeated questionnaires may place on ward staff members recruited to the study. Staff are required to provide weekly responses to questionnaires, and daily response to the brief well-being measure. The burden of these has been reduced as far as possible by the use of creative methods of data collection, such as using bespoke outcome measure items which are applicable to the individual and use of a token-voting system to record staff wellbeing to reduce time cost as far as possible. Staff and managers have been consulted about the burden of measures and have suggested that they feel this is not unreasonable.

Please circle your answer as appropriate:

ETHICAL ISSUES			
SA3	Bringing the University into disrepute Is there any aspect of the proposed research which might bring the University into disrepute? For example, could any aspect of the research be considered controversial or prejudiced?	*No*	***YES***
SA4	**Protection of research subject confidentiality** *Will you make every effort to protect research subject confidentiality by conforming to the University of Edinburgh's guidance on data security, protection and confidentiality as specified in:* www.ed.ac.uk/information-services/research-support/data-library/research-data-mgmt *For example, there are mutually understood agreements about:* (a) non-attribution of individual responses; (b) Individuals, and organisations where necessary, being anonymised in stored data, publications and presentations; (c) publication and feedback to participants and collaborators; (d) With respect to auto-ethnographic work it is recognised that the subject's anonymity cannot be maintained but the confidentiality of significant others must be addressed.	***NO***	*Yes*

The legal basis for all academic research using personal data is Article 6(1)(e) 'public task of the University', not consent. Please ensure that you do not rely on consent for the actual processing of research data.			
SA 5	**Data protection and consent to participate** *Will you make every effort to ensure the confidentiality of any data arising from the project by complying with* the University of Edinburgh's Data Management procedures (see http://www.ed.ac.uk/information-services/research-support/data-library/research-data-mgmt). For example (a) Ensuring any participants recruited consent to their data being collected, stored, archived and destroyed as appropriate; (c) Ensuring identifying information[7], (e.g. consent forms) is held separately from data and is only accessible by the chief investigator and their supervisors; (e) Ensuring there are no other special issues arising regarding confidentiality/consent. (f) Ensuring that where NHS data is being accessed Caldicott Guardian approval has been obtained. **IT IS NECESSARY TO GIVE THE HEAD OF SCHOOL'S NAME AS THE CONTACT PERSON IN CASE OF ANY COMPLAINT** **PLEASE MAKE SURE THAT THIS LINK IS PROVIDED on any Information sheet/consent form:** **(http://www.ed.ac.uk/files/imports/fileManager/WEB%20Complaint%20Form.pdf)**	***NO***	*Yes*
SA 6	**Duty to disseminate research findings** Are there issues which will prevent all participants and relevant stakeholders having access to a clear, understandable and accurate summary of the research findings should they wish?	*No*	***YES***

[7] 'Identifiable information' refers to information that would allow you to know, or be able to deduce, the identity of a patient. The most common examples of this would be accessing medical records or similar, or accessing a database that includes patients' names.

SA 7	**Moral issues and Researcher/Institutional Conflicts of Interest** *Are there any SPECIAL MORAL ISSUES/CONFLICTS OF INTEREST?* Examples include, but are not limited to: Where the purposes of research are concealed; Where respondents are unable to provide informed consent Where there is financial or non-financial benefit for *anyone* involved in the research, or for their relative or friend. Where research findings could impinge negatively or differentially upon participants or stakeholders (for example when selecting an unrepresentative sample of a larger population). Where there is a dual relationship between the researcher and subject? E.g. where the researcher is also the subject's practitioner or clinician. Where research involves covert surveillance or covert data collection. Where routinely collected data is used for research alongside novel data. **NOVEL DATA COLLECTION SHOULD NOT BE CONFLATED WITH ROUTINELY COLLECTED DATA. WHERE BOTH ARE BEING USED THIS NEEDS TO BE MADE CLEAR IN ANY COVERING LETTER, PARTICIPANT INFORMATION SHEET AND CONSENT FORM IN ORDER FOR INFORMED CONSENT TO BE POSSIBLE.**	*No*	***YES***
SA 8	Potential physical or psychological harm, discomfort or stress Is there any foreseeable potential for: significant psychological harm or stress for participants significant physical harm or discomfort for participants? significant risk to the researcher? Examples of issues/ topics that have the potential to cause psychological harm, discomfort or distress and should lead you to answer 'yes' to this question include, but are not limited to: *Relationship breakdown; bullying; bereavement; mental health difficulties; trauma / PTSD; Violence or sexual violence; physical, sexual or emotional abuse in either children or adults; feedback of results from the project's assessments.*	*No*	***YES***

SA 9	**Vulnerable participants** Will you be ***recruiting*** any participants or interviewees who could be considered vulnerable? Examples of vulnerable groups, the inclusion of which should lead you to answer yes to this question include, but are not limited to: Clients or patients of either the researcher OR the person recruiting subjects; Children & young people; people who are in custody or care for example, offenders, looked after children or nursing home resident; persons with mental health difficulties including those accessing self-help groups; auto-ethnographic researchers examining distressing topics.	*No*	***YES***

Level 1 Assessment outcome:

SA10 Have you circled any answers in <u>BOLD</u> typescript? Please tick as appropriate

No ☐ Your responses on the completed self-audit confirm the ABSENCE OF REASONABLY FORESEEABLE ETHICAL RISKS.

Please now read the guidance below and provide the required signatures.

You are NOT REQUIRED to complete the Level 2/3 sections of this form.

Please submit the UoE HSS Ethics Application Form electronic document (in its entirety) along with ALL additional required documentation, failure to do so will mean that your form is returned to you.

Yes ☒ Your responses on the completed self-audit indicate that we require further information to consider your application.

Read the Guidance below and provide the required signatures.

(ii) You **ARE REQUIRED** to complete the Level 2/3 application form.

(III) Please continue to the next part of this document where you will find the level 2/3/4 form

Subsequent to submission of this form, any alterations in the proposed methodology of the project should be reviewed by both the applicant and their supervisor. If the change to methodology results in a change to any answer on the form, then a resubmission to the Ethics subgroup is required.

The principal investigator is responsible for ensuring compliance with any additional ethical requirements that might apply, and/or for compliance with any additional requirements for review by external bodies.

ALL forms should be submitted in electronic format. Digital signatures or scanned in originals are acceptable. The applicant should keep a copy of all forms for inclusion in their thesis.

____Fiona Beaton ____	_____	__17/06/2019____
Applicant's Name	Applicant's Signature	Date

__Azucena Guzman____	_____	_____
19/06/2019		
_____	_____	_____
*Supervisor Signature[8]	Supervisor Name	Date

*NOTE to Supervisor: Ethical review will be based only on the information contained in this form. If countersigning this check-list as truly warranting all 'No' answers, you are taking responsibility, on behalf of the HSS and UoE, that the research proposed truly poses no ethical risks.

[8] Not required for staff applications

CONFIDENTIALITY AND HANDLING OF DATA

BEFORE COMPLETING THIS SECTION, PLEASE MAKE REFERENCE TO THE UNIVERSITY OF EDINBURGH'S DATA PROTECTION POLICY AND RESEARCH DATA PROTECTION GUIDANCE

ER1: What information about participants'/subjects' data will you collect and use? Please specify if any personal data will be collected.

The participants' names will be recorded on the consent form, which will be stored separately from the anonymised research data to ensure pseudonymisation. The participants' will be offered the opportunity to share their email address in order to receive survey reminders.

The demographic questionnaire will collect details of participants' jobs (role; length of time in position; contracted hours and recent working pattern) and personal information (age; gender; marital status and number of dependants).

Outcome measures will collect information of staff burnout, sense of competence in their job and sense of reciprocity with patients.

ER2: Will you collect or use NHS data?

If you are collecting or using NHS data you may require sponsorship and/or Caldicott Approval.

Please refer to the ACCORD (Academic and Clinical Central Office for Research and Development) website for more information.

No

ER3: Who will have access to the raw data?

The researcher (DClinPsy student), the academic supervisor and the clinical supervisor will have access to the raw data.

ER4: What training will staff who have access to the data receive on their responsibilities for its safe handling? All staff must complete the following mandatory Data Protection training available through the self-enrolment page on Learn:

Data Protection for Research (DP Training Research)

Data Protection Training

The researcher (DClinPsych student) has completed the University of Edinburgh Data Protection Training and the Data Protection for Research training. The supervisors have received data protection training through their professional roles.

The legal basis for all academic research using personal data is Article 6(1)(e) 'public task of the University', not consent. Please ensure that you do not rely on consent for the actual processing of research data.

ER5: Will the information include special categories of personal data?

These include:

health data

data relating to race or ethnicity

to political opinions or religious beliefs

trade union membership

criminal convictions

sexual orientations

genetic data

biometric data

☐ Yes

☒ No

If yes, go to ER7, if no, go to ER9.

Ensure that your legal basis for using one or more of these special categories of personal data in your research is Article 9(2)(j) – processing is necessary for research purposes.

ER6: How will the confidentiality of the data, including the identity of participants, be ensured? Is there a strategy in place to replace disclosive identifiers of an individual or entity from the data? Explain what safeguards e.g. technical or organisational you have in place, such as:

Compliance with the minimisation principle – use only the absolute minimum of personal data required for your purpose

Anonymising personal data if you can

If you cannot anonymise, wherever possible, pseudonymise all personal data

Storing the data securely

ER7: Do the systems you will be using to store your data comply with the University's Information Security Policy?

(see http://www.ed.ac.uk/information-services/about/policies-and-regulations/security-policies/security-policy)

YES/NO **If NO, explain why not.**

ER8: The new legal basis for conducting research is 'public task of the University'. For this reason researchers need to demonstrate how their research is in the public interest. Please indicate how your research has been demonstrated to be in the public interest using the options below.

☐ Your research is proportionate

☐ Your research is subject to a governance framework

☐ Your research has undergone review by a Research Ethics Committee (does not have to be a European REC)

☐ Your research has been peer reviewed by a funder

☐ Confidentiality Advisory Group (CAG) recommendation for support in England and Wales or support by the Public Benefit and Privacy Panel (PBPP) for Health and Social Care in Scotland

☐ Other (please indicate).

ER9: You must consult your collaborators before answering the following questions. It is essential that you identify and list all risks to the privacy of research participants. You will then need to consider the likelihood of the risks manifesting and the severity of harm if they do.

Risk	Likelihood of risk manifesting			Severity of harm		
	Remote	Possible	Probable	Minimal	Significant	Severe
Identifiable due to data linkage	✓	☐	☐	☐	✓	☐
Identifiable due to low participant numbers	☐	✓	☐	☐	✓	☐
Identifiable due to geographical location	☐	✓	☐	☐	✓	☐
Identifiable due to transfer of data	✓	☐	☐	☐	✓	☐
Identifiable due to access of data	✓	☐	☐	☐	✓	☐
Insert more rows as appropriate	☐	☐	☐	☐	✓	☐

ER10: Please identify measures you could take to reduce or eliminate the risks identified as possible/significant or probable/severe?

The risk of patients being identified due to low participant numbers and / or the limited location in which the study is conducted will be reduced due to pseudonymisation of the data

This will also be taken in to account in the presentation of the results of the study to ensure that the findings, particularly those from the qualitative aspect of the study are presented in such a way, as to not identify any participants.

ER11: Will information containing personal, identifiable data be transferred to, shared with, supported by, or otherwise available to third parties outside the University?

☒ Yes

☐ No

If yes go to ER12 if no go to ER13

ER12: Please explain why this necessary and how the transfer of the information will be made secure. If the third party is based outside the European Economic Area please obtain guidance from the Data Protection Officer.

Data transfer between the NHS and the University of Edinburgh is necessary to ensure the accurate analysis of the data and to allow the academic supervisor oversight of this aspect of the study. Secure transfer will be ensured through the use of NHS Secure Electronic File Transfer (SEFT), providing encryption throughout the process.

ER13: Other than the use by third parties under section 5.7, will the data be used, accessed or stored away from University premises?

☐ Yes

☒ No

If yes go to ER14 and no go to ER15

ER14: Describe the arrangements you have put in place to safeguard the data from accidental or deliberate access, amendment or deletion when it is not on University premises, including when it is in transit, and (where applicable) it is transferred outside the EEA.

ER15: Will feedback of findings be given to your research project participants?

☒ Yes

☐ No

ER16: Describe the physical and security arrangements you will put in place for the data.

Staff member's questionnaire responses will only be identifiable by their participant identification number. When completed, questionnaire responses will be placed in a tamper-evident box within a secure staff area of the ward. These responses will be collected once per week by the research team and transferred to a locked filing cabinet in the Psychology Department of NHS Dumfries and Galloway, Mountainhall Treatment Centre, Dumfries, which the principal investigator and clinical supervisor will have access to. As soon as practically possible, the data will be transferred to a data analysis program to be stored securely on a password protected NHS computer

Staff consent forms will be stored in a locked filing cabinet in the Psychology Department of NHS Dumfries and Galloway, Mountainhall Treatment Centre, Dumfries, in a separate location from the pseudo-anonymised questionnaire responses.

ER17: How do you intend the results of your research project to be used?

The project in its entirety will be submitted in partial fulfilment of the principal investigator's Doctorate in Clinical Psychology, and as such, the thesis will then be available through the Department of Clinical Psychology Thesis Database, providing open access to the results of the study.

The principal investigator will further seek to prepare the findings of both the systematic review and the empirical research for publication in a peer-reviewed academic journal. The principal investigator shall also seek opportunities to present the findings of the study at relevant academic conferences, such as the Alzheimer's Society Conference.

It is intended to present the findings of the findings of the study to stakeholders within NHS Dumfries and Galloway. The principal investigator will also endeavour to share the results of the study directly with the staff group from which the participants were recruited, either through a short, written summary or through a presentation at team meetings. There may be scope for publicising the findings of the research more widely through local media outlets, due to the innovative nature of the technology being used.

The principal investigator will also endeavour to consult with both the local patient experience group and the Scottish Dementia Working Group. Advice will be sought from them regarding other potential avenues for broader dissemination.

ER18: Does your project involve using secondary data?

☐ Yes

☒ No

ER19: Is this reuse compatible with what the data subjects were originally told about the use of their data? (e.g. were they told that it would be destroyed at the end of the study?)

☐ Yes

☐ No

N/A

ER20: Is it likely that someone could be identified from this data?

It is extremely difficult to make something totally anonymous, so even with secondary data there may be a need to apply security and access restrictions to it.

☐ Yes

☐ No

N/A

ER21: Specify where the data files/audio/videotapes etc. will be retained after the study, how long they will be retained and how they eventually will be disposed of?

Anonymised data will be securely stored long-term on the University of Edinburgh's long-term data storage repository datastore (DataVault). The academic supervisor will have access to the data in order to ensure its ongoing secure management. The data will initially be stored for a period of five years, after which point its storage will be reviewed to determine if further storage is required. If not, the data will be permanently deleted from the datastore.

Please note: Research data can be stored indefinitely as long as it is stored securely. For storage guidance please refer to LINK TO DATAVAULT/UNIVERITY STORAGE INFORMATION

For more information regarding data linkage in evaluating interventions for the benefit of the population's health, please see:
http://www.gov.scot/Topics/Statistics/datalinkageframework

Your application at this level is likely to require additional documentation, for example a Data Storage Plan, consent forms or participant information sheets. Please return to the Documentation Checklist on page 2 to list your supporting documentation.

LEVEL 2/3 ETHICAL REVIEW

Complete only if indicated in the conclusion of your Level 1 form. Applications will be monitored and audited to ensure the School Ethics Policy and procedures are complied with and applicants contacted in cases where there are concerns or queries. Research must not proceed before ethical approval has been granted. For this reason it is particularly important that applications are submitted well in advance of any required date of approval.

If the answer to any of the questions below is 'yes' please elaborate and give details of how the issue will be addressed to ensure ethical standards are maintained. The response boxes will expand as you complete them. Forms not containing sufficient detail will be returned incurring delay.

SECURITY-SENSITIVE MATERIAL

ER22 Does your research fit into any of the following security-sensitive categories? If so, indicate which.

YES/**NO** **Commissioned by the military**

YES/**NO** **Commissioned under an EU security call**

YES/**NO** **Involve the acquisition of security clearances**

YES/**NO** **Concern groups which may be construed as terrorist or extremist**

IF YOU HAVE ANSWERED YES TO ANY OF THESE CONTINUE TO ER23. IF YOU HAVE ANSWERED NO TO ALL OF THESE QUESTIONS MOVE TO ER28.

ER23 The Terrorism Act (2006) outlaws the dissemination of records, statements and other documents that can be interpreted as promoting or endorsing terrorist acts.

YES/NO Does your research involve the storage on a computer of such records, statements and other documents?

YES/NO Might your research involve the electronic transmission (e.g. as an email attachment) of records or statements?

IF YOU ANSWERED YES TO ANY OF THESE YOU ARE ADVISED TO STORE THE RELEVANT RECORDS OR STATEMENTS ELECTRONICALLY ON A SECURE UNIVERSITY FILE STORE. THE SAME APPLIES TO PAPER DOCUMENTS WITH THE SAME SORT OF CONTENT. THESE SHOULD BE SCANNED AND UPLOADED.

ACCESS TO THIS FILE STORE WILL BE PROTECTED BY A PASSWORD UNIQUE TO YOU AND YOUR SCHOOL RESEARCH ETHICS OFFICER. PLEASE INDICATE THAT YOU AGREE TO STORE ALL DOCUMENTS RELEVANT TO THESE QUESTIONS ON THAT FILE STORE:

YES/NO

ER24 Please indicate that you agree not to transmit electronically to any third party documents in the document store:

YES/NO

ER25 Will your research involve visits to websites that might be associated with extreme or terrorist organisations?

YES/NO

ER26 If you answer YES to ER18 you are advised that such sites may be subject to surveillance by the police. Accessing those sites from University IP addresses might lead to police enquiries. Please acknowledge that you understand this risk:

YES/NO

ER27 By submitting to the research ethics process, you accept that your School Research Ethics Officer and the convenor of the University's Compliance Group will have access to a list of titles of documents (but not the content of documents) in your document store. Please acknowledge that you accept this.

YES/NO

Countersigned by supervisor/manager:

Name:

Date:

RISKS TO, AND SAFETY OF, RESEARCHERS NAMED IN THIS APPLICATION

ER28: Do any of those conducting the research named above need appropriate training to enable them to conduct the proposed research safely and in accordance with the ethical principles set out by the College?

YES / **NO**

ER29: Are any of the researchers likely to be sent or go to any areas where their safety may be compromised, or they may need support to deal with difficult issues?

YES / NO

Data collection will take place on a locked dementia care ward. There is a minimal risk that researchers may be exposed to behaviour which is perceived as challenging and which may require them to deal with difficult issues, however, this is not out with the risk which would be faced when carrying out normal duties associated with their roles on the ward. Highly trained nursing staff will be present at all times during the researcher's presence on the ward who will be able to intervene in any challenging situations.

ER30: Could researchers have any conflicts of interest?

YES / **NO**

RISKS TO, AND SAFETY OF, PARTICIPANTS

ER31: Are any of your participants children or protected adults (protected adults are those in receipt of registered care, health, community care or welfare services. Anyone who will have contact with children or protected adults requires approval from Disclosure Scotland at http://www.disclosurescotland.co.uk/

Do any of the researchers taking part in this study require Disclosure Scotland approval? (√)

Not applicable	
Relevant researcher/s has current Disclosure Scotland approval through a current NHS employment contract	✓
Yes *(ethical approval will be subject to documentation confirming Disclosure Scotland approval with this form)*	

ER32: Could the research induce any psychological stress or discomfort?

YES / NO

The topics in the participant outcome measures may be emotive for some members of staff, as they will be asked to consider the nature of their professional relationships with their patients and their own psychological wellbeing. The research may highlight difficulties which are already present in these areas, increasing an individual's awareness of them.

In order to mitigate this risk, information sheets provided to staff participants will encourage them to speak with senior colleagues or supervisors if they have concerns about topics raised in the study. The principal investigator (PI) will be present on the ward regularly throughout data collection phases, and as a second and third-year trainee clinical psychologist has clinical experience in assessing and containing psychological distress. The staff liaison, a senior member of ward staff, will meet regularly with the PI to provide updates and highlight any areas of concern regarding staff interaction with the outcome measures. The PI will work in close contact with the project's clinical supervisor (a qualified consultant clinical psychologist) in the management of any staff distress and information regarding relevant support (such as occupational health services and professional supervision) will be made available to staff at all points of the study.

ER33: Does the research involve any physically invasive or potentially physically harmful procedures?

YES / **NO**

ER34: Could this research adversely affect participants in any other way?

YES / NO

There is also a potential issue of the burden regular and repeated questionnaires may place on ward staff members recruited to the study. Staff are required to provide weekly responses to questionnaires, and daily response to the brief well-being measure. The burden of these has been reduced as far as possible by the use of creative methods of data collection, such as using bespoke outcome measure items which are applicable to the individual and use of a token-voting system to record staff wellbeing to reduce time cost as far as possible. Staff and managers have been consulted about the burden of measures and have suggested that they feel this is not unreasonable.

RESEARCH DESIGN

ER35: Does the research involves living human subjects specifically recruited for this research project

If 'yes' please complete the rest of this section.

YES / NO

ER36: How many participants will be involved in the study?

Ten participants will be recruited to the study

ER37: What criteria will be used in deciding on inclusion/exclusion of participants?

Inclusion Criteria

Registered nurses (any grade) and Health Care Assistants (HCAs) who routinely work exclusively on Cree ward.

Able to read and speak English fluently

Able to commit to the project for 24 weeks

Aged over 16 years of age

Exclusion criteria

Temporary staff expected to be on the ward for less than 24 weeks.

Senior nurse managers who do not routinely work on the ward

Nursing students on placement within the ward (due to them not being fully integrated into the culture on the ward.)

Staff who do not routinely work on Cree Ward (i.e. temporary cover from other wards)

Members of staff who visit the ward but do not solely work there (e.g. medical staff/psychologists/ allied health professionals)

ER38: How will the sample be recruited? (E.g. posters, letters, a direct approach- specify by whom.)

A minimum of ten staff members will be recruited from those nurses and Health Care Assistants (HCAs) who regularly work on Cree ward. Posters and information leaflets will be distributed within staff areas in the ward to inform potential participants of the study. The principal investigator shall also attend team meetings on the ward to raise awareness of the project and answer any questions staff may have about participation A senior member of ward staff will be identified to act as staff liaison to further support the project. Approval for staff participation has been gained from senior managers within the hospital.

NHS senior managers in Dumfries and Galloway are supportive of research being carried out on the ward and will encourage staff to participate. The principal investigator (PI) will have regular access to hospital ward staff and carry out regular visits to encourage participation. Staff will be briefed that the research seeks to represent their experiences it is hoped staff will be interested in engaging with this project as a way of sharing their views of their workplace. To further encourage compliance with the regular data collection within the busy ward environment, staff will be offered the incentive of inclusion in a prize draw to win a £40 gift voucher to a retailer of their choice if they complete 90% or more of the required questionnaires.

ER39: Will the study involve groups or individuals who are in custody or care, such as students at school, self-help groups, or residents of nursing home?

YES / **NO**

ER40: Will there be a control group?

YES / **NO**

ER41: What information will be provided to participants prior to their consent? (e.g. information leaflet, briefing session)

YES / NO

Posters will be placed in staff areas of the ward to inform participants of the study. All potential participants will be provided with an information sheet (attached) which describes their involvement in the study and how the collected data will be used. The principal investigator will be present on the ward at regular intervals, including team meetings to provide information and answer any questions in relation to the study.

ER42: Participants have a right to withdraw from the study at any time. Please tick to confirm that participants will be advised of their rights, including the right to continue receiving services if they withdraw from the study. YES ✓

ER43: Will it be necessary for participants to take part in the study without their knowledge and consent? (e.g. covert observation of people in non-public places)

YES / **NO**

ER44: Where consent is obtained, what steps will be taken to ensure that a written record is maintained?

Participants will complete a written consent form which will be retained and stored securely (in a separate physical location to study data) for the duration of the study.

ER45: In the case of participants whose first language is not English, what arrangements are being made to ensure informed consent?
Only participants who are fluent in English will be recruited to the study.
ER46: Will participants receive any financial or other benefit from their participation?
YES / NO To encourage compliance with the regular data collection within the busy ward environment, staff shall be offered the incentive of inclusion in a prize draw to win a £40 gift voucher to a retailer of their choice if they complete 90% or more of the required questionnaires. This incentive is clearly explained in the participant information sheet.
ER47: Are any of the participants likely to be particularly vulnerable, such as elderly or disabled people, adults with incapacity, your own students, members of ethnic minorities, or in a professional or client relationship with the researcher?
YES / NO Participants will have a professional relationship with the researcher as a member of the clinical team who may work with patients on the ward. The researcher has no supervisory or line management responsibilities for any potential participants and the extent of their professional contact with each other is likely to be very limited out with the study, therefore there is not felt to be a conflict between these roles.
ER48: Will any of the participants be under 16 years of age?
YES / **NO**
ER49: Will any of the participants be interviewed in situations which will compromise their ability to give informed consent, such as in prison, residential care, or the care of the local authority?
YES / **NO**

BRINGING THE UNIVERSITY INTO DISREPUTE
ER50: If on the level one form you have answered YES that some aspect of the proposed research "might bring the University into disrepute", please elaborate alongside how this might arise, and what steps will be taken by the researcher to mitigate and/or manage this, to minimise adverse consequences to the University.
N/A

Subsequent to submission of this form, **both the applicant and their supervisor should review any alterations in the proposed methodology of the project.** If the change to methodology results in a change to any answer on the form, then a resubmission to the Ethics subgroup is **required.**

The principal investigator is responsible for ensuring compliance with any additional ethical requirements that might apply, and/or for compliance with any additional requirements for review by external bodies.

ALL forms should be submitted in electronic format. Digital signatures or scanned in originals are acceptable. The applicant should keep a copy of all forms for inclusion in their thesis.

__Fiona Beaton ____	_____	___17/06/19__
Applicant's Name	Applicant's Signature	Date
	____Azucena Guzman__	____19/06/19_
*Supervisor Signature[9]	Supervisor Name	Date

*NOTE to Supervisor: Ethical review will be based only on the information contained in this form. If countersigning this check-list as truly warranting all 'No' answers, you are taking responsibility, on behalf of the HSS and UoE, that the research proposed truly poses no ethical risks.

ER51: ISSUES ARISING FROM THE PROPOSAL

[9] Not required for staff applications

I can confirm that the above application has been reviewed by two independent reviewers. It is their opinion that:

Ethical issues have been satisfactorily addressed and no further response from the applicant is necessary,

Signature:

Position: Lecturer in Clinical Psychology, Ethics & Integrity Lead

Date: 12/07/2019

ER52 APPLICANT'S RESPONSE (If required)

Signature:

Date:

ER53 CONCLUSION TO ETHICAL REVIEW (if required)

The applicant's response to our request for further clarification or amendments has now satisfied the requirements for ethical practice and the application has therefore been approved.

Signature:

Position:

Date:

ER54 AMENDMENT/S: REQUEST FOR APPROVAL

Subsequent to receipt of ethical approval above, I, the applicant, would like to request the following amendment/s to my original proposal. Signature: Date:
ER55 CONCLUSION TO ETHICAL REVIEW OF AMENDMENT
I can confirm that the above amendment has been reviewed by two independent reviewers. It is their opinion that: Ethical issues have been satisfactorily addressed and no further response from the applicant is necessary, OR The ethical issues listed below arise and the following steps are being taken to address them: Signature: Position: Date:

Acronyms / Terms Used

NHS: National Health Service

SHSS: School of Health in Social Science

IRAS: Integrated Research Applications System

Section: The SHSS is divided into Sections or subject areas, these are; Nursing Studies, Clinical Psychology, C-PASS.

Ethics Administrators

Nursing Studies: nursing@ed.ac.uk

Counselling, Psychotherapy and Applied Social Science: CPASS.ethics@ed.ac.uk

Clinical Psychology: Submitting.Ethics@ed.ac.uk

MA in Health, Science and Society: mahssug@ed.ac.uk

School of Health in Social Science
Clinical and Health Psychology

The University of Edinburgh
Medical School
Doorway 6, Teviot Place
Edinburgh EH8 9AG

Telephone 0131 651 3969
Fax 0131 650 3891
Email submitting.ethics@ed.ac.uk

Fiona Beaton
Trainee Clinical Psychologist (DClinPsychol)
Department of Clinical and Health Psychology
School of Health in Social Science
University of Edinburgh

30 July 2019

Dear Fiona,

Application for Level 2 Approval

Reference: CLIN649
Project Title: A mixed-method multiple-baseline single-case study exploring the impact of the Tovertafel (Magic Table) on staff burnout in an acute dementia care hospital ward.
Academic Supervisor: Azucena Guzman

Thank you for submitting the above research project for review by the Department of Clinical and Health Psychology Ethics Research Panel. I can confirm that the submission has been independently reviewed and was approved on the 12th July 2019.

Should there be any change to the research protocol it is important that you alert us to this as this may necessitate further review.

Yours sincerely,

Kirsty Gardner
Administrative Secretary
Clinical Psychology

Appendix J – NHS Management approval

Research and Development Support Unit
Ground Floor
Dumfries and Galloway Royal Infirmary
Bankend Road
Dumfries
DG1 4AP

NHS
Dumfries
& Galloway

Ms Fiona Beaton
Trainee Clinical Psychologise
Department of Psychological Services & Research
First Floor East,
Mountainhall Treatment Centre
Dumfries
DG1 4GG

Date: 30TH August 2019

Our ref: JC/TC/19/DGY/009
Study title: IMPACT OF THE TOVERTAFEL ON STAFF BURNOUT
Protocol version approved: v2 Dated: 31/05/2019
Amendment (up to and incl.): N/A

Dear Ms Beaton

Thank you for sending me details of your study with a request for management approval. I can confirm that the study review team has reviewed the documentation and on this basis I am pleased to inform you that your study has management approval for commencement within NHS Dumfries and Galloway.

It is a condition of this approval that everyone involved in this study abides by the guidelines/protocols laid down by this Health Board in respect of confidentiality and Research Governance. It is your responsibility to ensure you are familiar with these; please do not hesitate to seek advice if you are unsure. Copies of Research Governance Framework documents are available via the website www.sehd.scot.nhs.uk/cso and then use the publications link.

We also note that it is the sponsor's responsibility to ensure that appropriate training is in place for all local investigators. It is important that all research must be carried out in compliance with the Research Governance Framework for Health and Community Care and the new EU Clinical Trials Directive (for clinical trials involving investigational medicinal products).

As part of the Health Board's responsibilities under Research Governance a sample of studies will be monitored, and it is therefore important that all records in connection with the study are kept up to date and available for review. We are also required to inform you that details of your study will be entered onto our R&D database. As custodian of the information collated during this research project, you are responsible for ensuring the security of all personal information collected, in line with NHS Scotland IT Security Policies, until the destruction of this data.

If your study is adopted by UKCRN into a portfolio then please advise this department of recruitment figures by adding accrual data to that database on a monthly basis.

Please notify the R&D office immediately you become aware of any serious adverse events associated with this research.

Research and Development Support Unit
Ground Floor
Dumfries and Galloway Royal Infirmary
Bankend Road
Dumfries
DG1 4AP

NHS
Dumfries
& Galloway

You must contact the R&D Department if/when the project is subject to any minor or substantial amendments so that these can be appropriately assessed, and approved, where necessary. I understand that performance of this study will not infringe on NHS Dumfries and Galloway's ability to deliver our usual level of service.

I take this opportunity to wish you every success with your project. Please do not hesitate to seek help and advice from the R&D Support Unit (ext 33165/33815) if there is anything you feel you require assistance with. I look forward to hearing about your work and would appreciate a short annual report and a final report when the study is complete.

Yours sincerely

Mrs Janie Candlish
Clinical Trials/Research Project Manager

cc: SREDA Database
Ms Charlotte Smith

Appendix K – PAND Step by step instructions

Extract from Guzmán et al (2016):

"Statistical analysis

Participants' behavioral scores were plotted for each bespoke DMAS-17 item. This visual analysis considered level, trend line, and variability differences between phases A-B-C (baseline, intervention, and follow-up effects). A statistical analysis of the trends between Phase A and B was undertaken using PAND. PAND has been developed in the field of special education (Parker *et al.*, 2007), self-practice in Cognitive Behavioral Therapy (Davis, 2008) and social skills in autistic children (Schneider *et al.*, 2008).

PAND examines the number of observations from baseline overlapping with observations in the intervention (Parker and Hagan-Burke, 2007a; Parker and Hagan-Burke, 2007b; Parker *et al.*, 2007). The objective is that the lowest data cluster (0 = none) of the outcome measure is scored in Phase B.
A six step approach was applied:

Step 1: using the data from Participant J with 21 days baseline (see Figure 1, low self-esteem) as an example, it can be seen that still data clusters (scores of 2 and 4) between the Phase A (baseline) and Phase B (intervention) are not "widely separated" and overlap is apparent. Overlapping data points are defined as the "minimum number that would have to be swapped across phases for complete score separation" (Parker *et al.*, 2007, p. 197). As there is no score in Phase A below 2, all the remaining scores in Phase B are non-overlapping. In this example, "2" is the non-overlapping cut-off value.

Step 2: create spreadsheet to calculate PAND. To assess the number of overlapping data clusters (scores) for each participant, all observations were labeled in a spreadsheet (Microsoft Excel) as to whether they originated in Phase A or Phase B, and then were sorted into descending order of magnitude (i.e. higher: 6, 4, 2 and lower: 0). See Table S1, published as supplementary material online attached to the electronic version of this paper at http://journals.cambridge.org/ipg to follow this self-esteem example. This followed the observed downward trend where low self- esteem ratings appeared to be higher in the baseline phase and decreased during the intervention phase although the highest cluster for low self-esteem was observed during the intervention phase (day 56).

Step 3: obtain data from figure to calculate PAND. Once data had been sorted, data clusters would have to be swapped across phases to allow for a complete separation of scores. There were eleven observations scored during Phase B intervention (6, 6, 4, 4, 4, 4, 2, 2, 2, 2, 2) overlapping with Phase A (baseline). In Table S1 (scores in italics and bold), the example given with participant J's self-esteem ratings illustrates where a line is drawn in order to allow complete separation of phases A and B, scores that were not "0" in Phase B (intervention). See Figure 1 and Table S2, published as supplementary material online attached to the electronic version of this paper at http://journals.cambridge.org/ipg to follow this self-esteem example. PAND equals the remaining data (higher scores in Phase A & lower scores in Phase B) divided by the total data observations N: 21 + 73 = 94/105 = 90 % where 50% is chance level (meaning that only 40% of self-esteem data in self-esteem

overlap). Parker *et al*. (2011) recommends rescaling PAND by the formula ((non-overlap/0.5) – 1) to facilitate a comparison with more familiar indicators.

Step 4: calculate Phi (bona fide effect size) and confidence intervals (CIs). A further method of assessing significance of overlap is by using Pearson's Phi coefficient. To do this one must "balance the table" with the higher/lower values. Parker *et al*. (2007) recommends doing to provide a robust approach for small differences by equating the overlap diagonals: 0 + 11 = 11/2 = 5.5 (lower scores in Phase A and higher scores in Phase B). Then, a 2 x 2 table with the higher and lower scores of Phase A and B, respectively, for each behavioral/mood item was constructed using SPSS Version 17. These tables were generated to establish PAND and to provide a "bona fide" ES for scores across Phases A versus B, which were entered into an online resource (Pezzullo, 2010 http://statpages.org/ctab2x2.html) to calculate Phi and its CIs. See Table S2, published as supplementary material online attached to the electronic version of this paper at http://journals.cambridge.org/ipg to follow example.

Step 5: interpret Effect Size (ES-magnitude of change). A major challenge in SCR is the need for interpretational guidelines for ES. Previous authors have warned on differences in ES magnitudes according to study design, client, and type of intervention (Rosnow and Rosenthal, 1989). In contrast to the interpretation of p-value significance, there is a "lack of ES guidelines" in SCR (Parker and Brossart, 2003) and the usual ES (small, medium, large) indicators developed by Cohen (1988) for common statistics do not apply and do not fit SCR data as the ES are larger. The most appropriate ways of classifying ES are derived from a sample of published SCR studies based on N=200 phase comparisons (Parker *et al*., 2011) to benchmark the magnitude of change for PAND and Phi in each participant. See supplementary Table S3, example published as supplementary material online attached to the electronic version of this paper at http://journals.cambridge.org/ipg). An empirically derived criteria based on actual SCR was applied. It is ultimately an arbitrary set of cases selected by Parker and colleagues and it is likely to be biased towards larger effects because studies showing effects detectable by visual analysis are more likely to be published. Most published and unpublished SCR studies do not use statistics; smaller effects not clear through visual analysis are less likely to be published. The 95% CIs obtained for the Phi scores based on N=69 sample (Parker *et al*., 2007b) were as follows: 10th percentile (- 0.02<. 22<. 44); 25th percentile (0.26< 0.51< 0.68); at 50th percentile (0.47< 0.68< 0.82); at 75th percentile (0.71< 0.86< 0.94); and at 90th percentile (0.79< 0.94< 0.99). This was considered a better alternative to inappropriate use of Cohen's conventional ES for SCR.

Step 6: to obtain a summary of the intervention effectiveness, we completed two meta-analysis to aggregate the ES of treatment across all the participants, one for mood and one for behavior. Parker and Vannest (2012) and Burns (2012) suggest conducting meta-analysis to provide an overall summary of the effect of the intervention in SCR. We aggregated the DMAS-17 for each participant with the most severe items from both the categories of mood and behavior at Phase A. It was meant by "severe", those items that scored the highest data clusters at baseline. Then the ES derived from each participant's individualized items were combined and computed using the WINPEPI programme COMPARE2.EXE (Abramson, 2011a; Abramson, 2011b), a procedure for comparison of two independent groups or samples (http://www. brixtonhealth.com/pepi4windows.html) by enter- ing the Phi coefficients obtained for the mood and behavior related items. " (Guzmán et al 2016 p1706-1708)

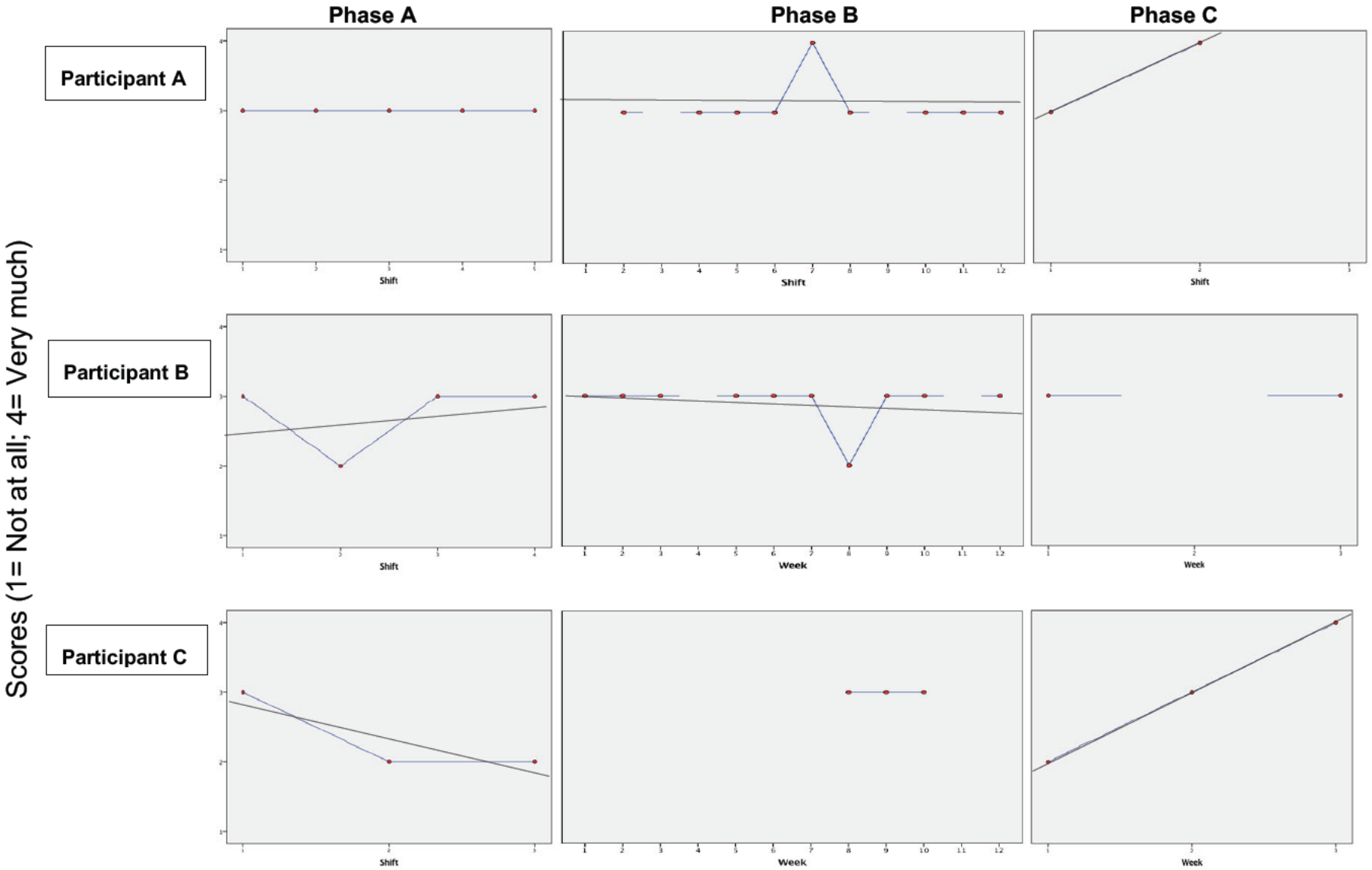
Appendix L - PAND and Phi effect size table

Reproduced from Parker et al. (2011) and Guzman et al. (2016)

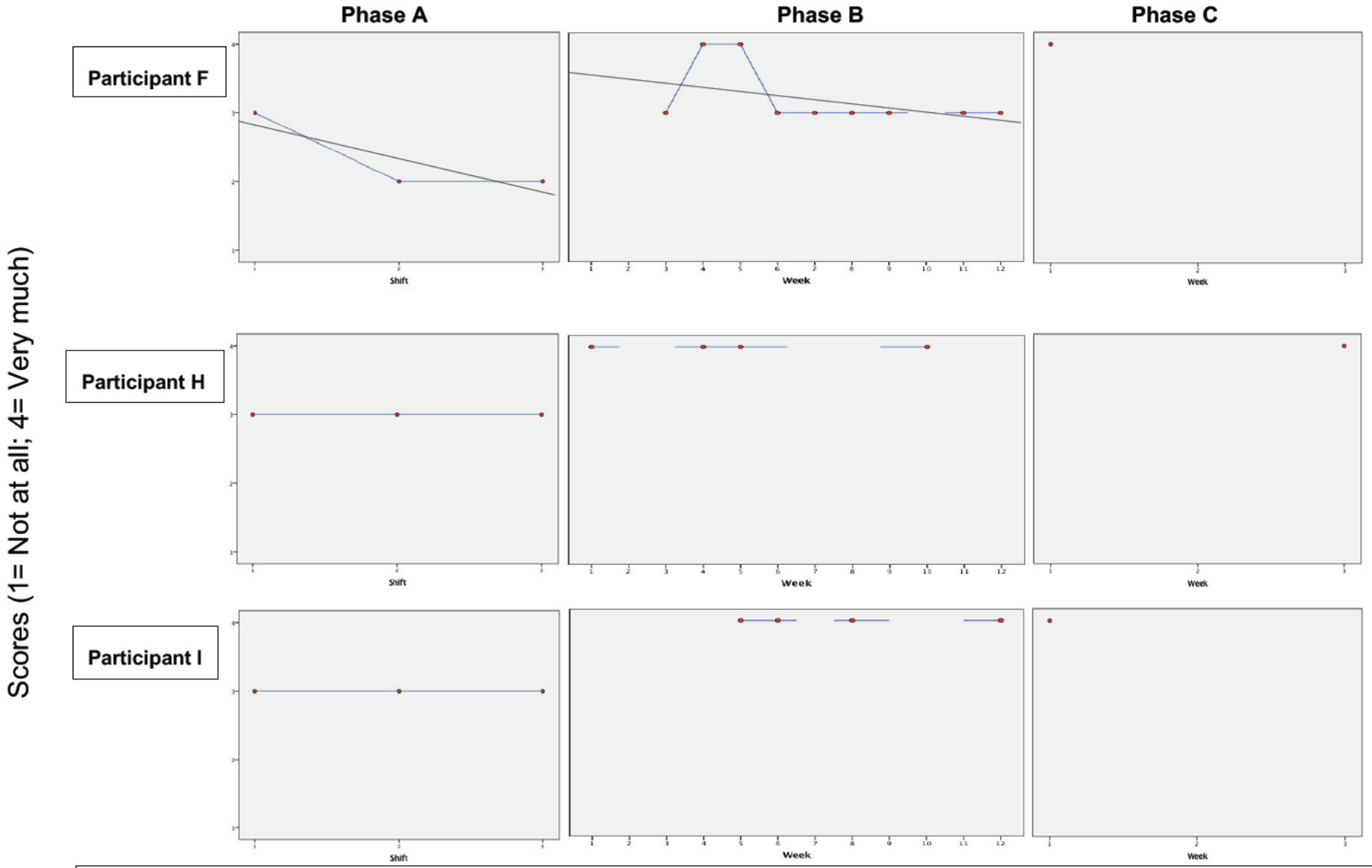
Percentiles	PAND (0-100)	Phi (0-100)	Effect Size
10th	0.20	0.26	small
25th	0.38	0.49	small
50th	0.64	0.72	medium
75th	0.86	0.83	large
90th	1.00	0.95	large

These percentile values are used to interpret the magnitude of change for PAND and Phi. The effect size magnitude changes into three categories – ‘small’, ‘medium’ and ‘large.

Appendix M – Graphs of responses to "How well do you feel you can offer stimulation (for the mind, the senses and the body) to a person with dementia in your daily work?" item by participant



Graphs show the participant responses to the item: "How well do you feel you can offer stimulation (for the mind, the senses and the body) to a person with dementia in your daily work?" at Baseline (Phase A), Intervention (Phase B) and Follow up (Phase C). Frequency of measurement in Phase A was on a shift by shift basis, and weekly on Phases B & C. Baselines were randomly allocated at 3,4, or 5 consecutive shifts. Higher scores indicate feeling more able to offer stimulation.



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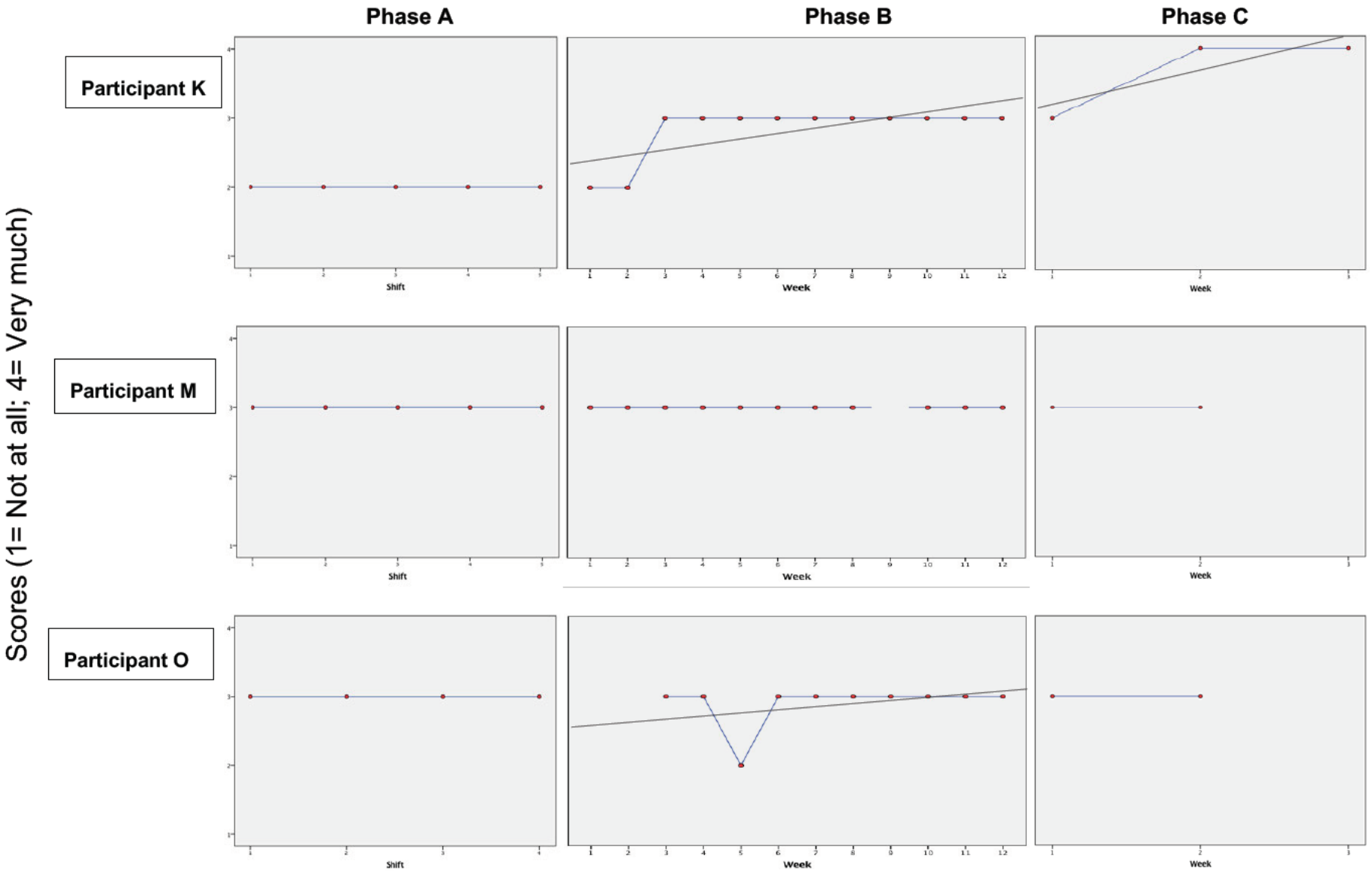
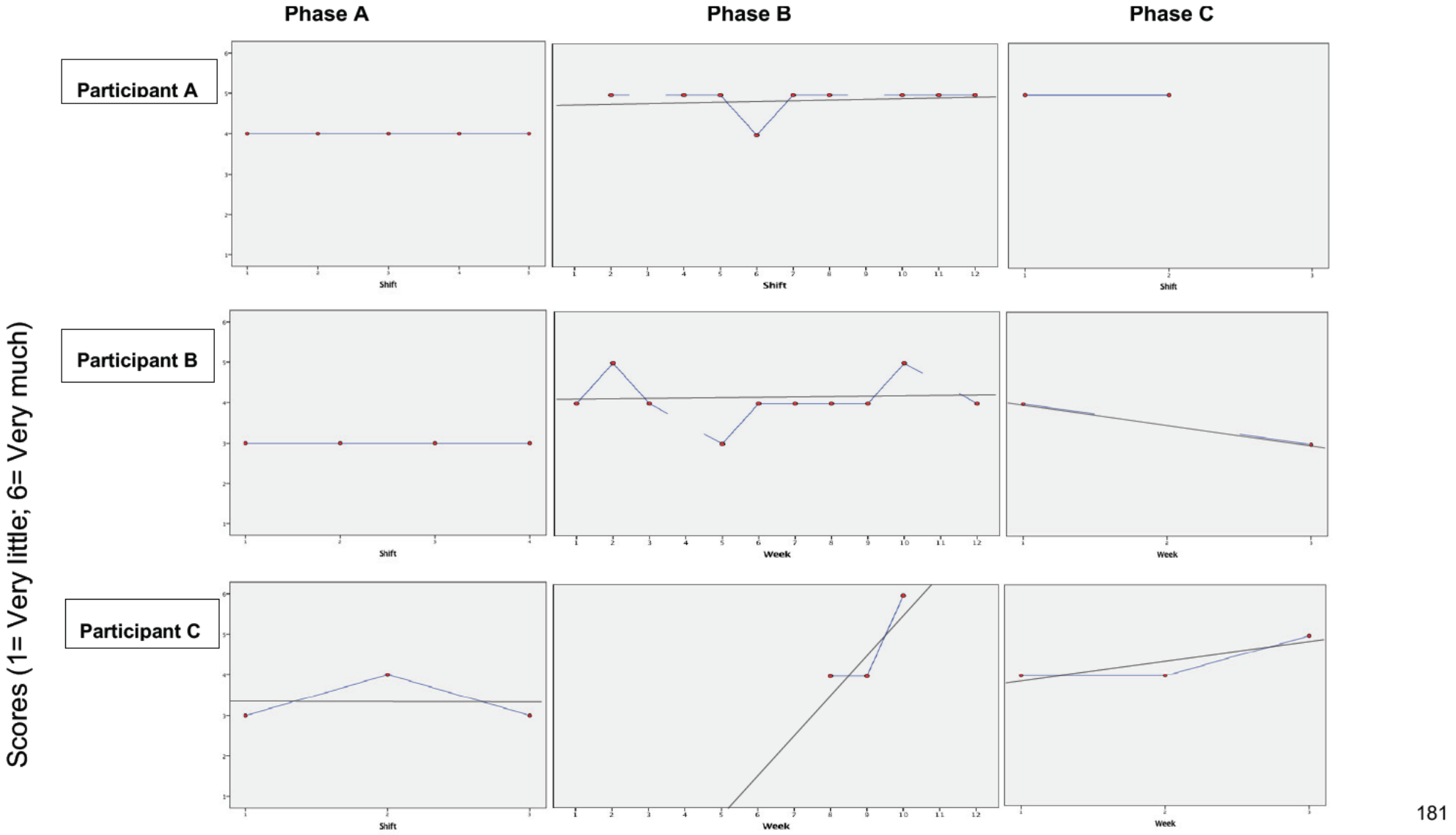
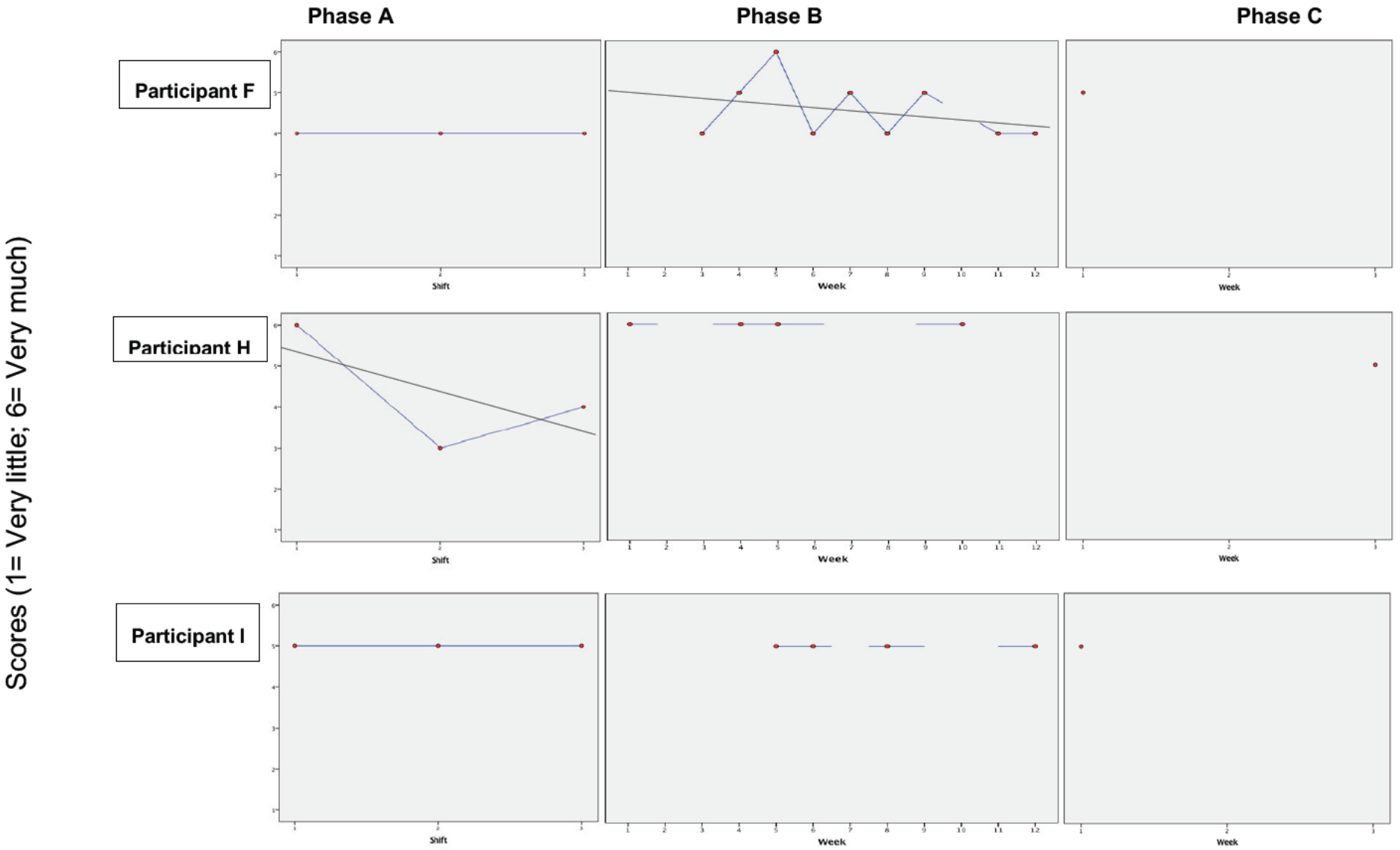


Graphs show the participant responses to the item: “How well do you feel you can offer stimulation (for the mind, the senses and the body) to a person with dementia in your daily work?” at Baseline (Phase A), Intervention (Phase B) and Follow up (Phase C). Frequency of measurement in Phase A was on a shift by shift basis, and weekly on Phases B & C. Baselines were randomly allocated at 3,4, or 5 consecutive shifts. Higher scores indicate feeling more able to offer stimulation.

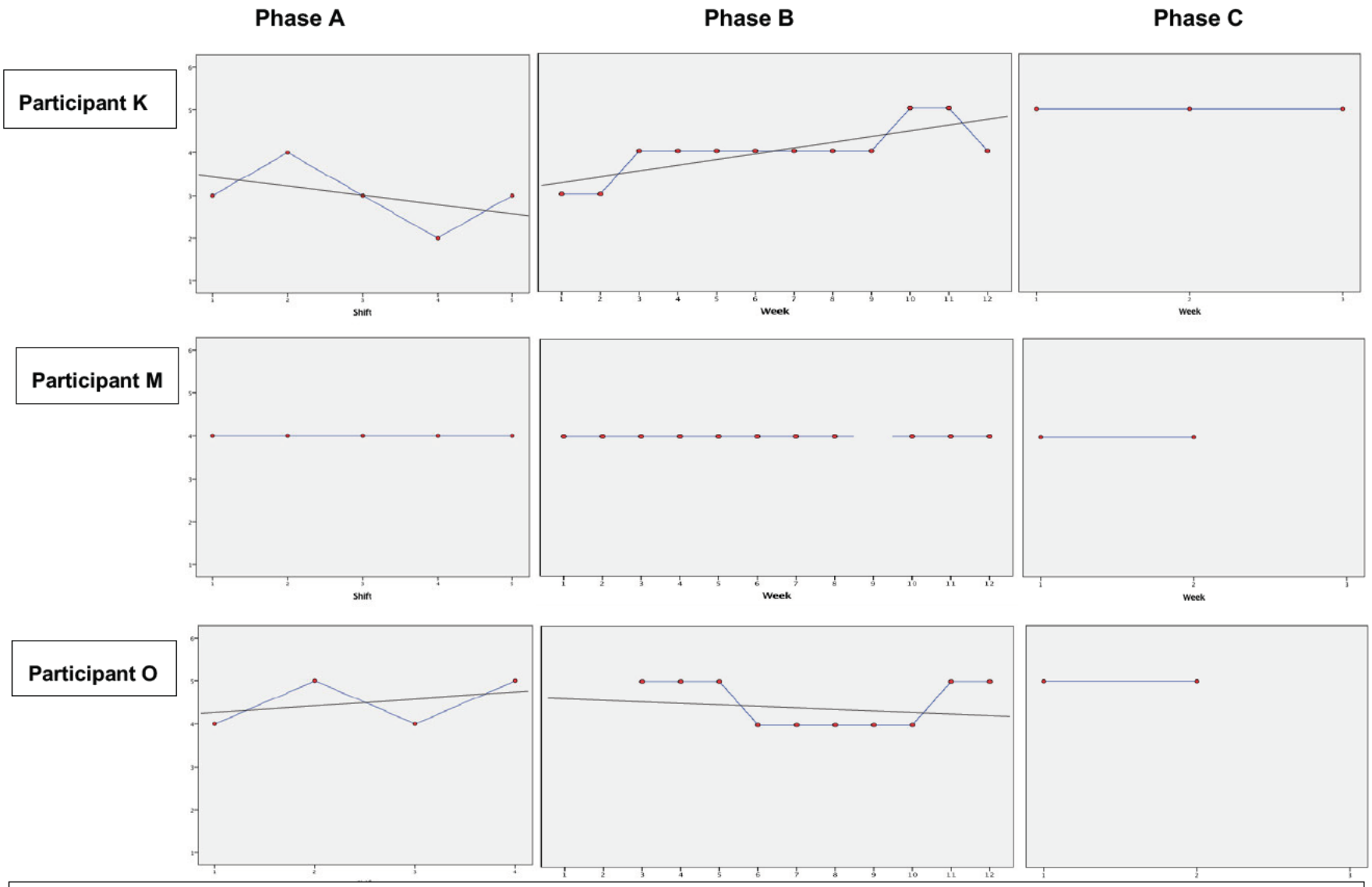
Appendix N – Graphs of responses to "How much appreciation do the older adults in your care have for you?" item by participant



Graphs show the participant responses to the item: "How much appreciation do the older adults in your care have for you?" at Baseline (Phase A), Intervention (Phase B) and Follow up (Phase C). Frequency of measurement in Phase A was on a shift by shift basis, and weekly on Phases B & C. Baselines were randomly allocated at 3,4, or 5 consecutive shifts. Higher scores indicate feeling more appreciated.



Graphs show the participant responses to the item: “How much appreciation do the older adults in your care have for you?” at Baseline (Phase A), Intervention (Phase B) and Follow up (Phase C). Frequency of measurement in Phase A was on a shift by shift basis, and weekly on Phases B & C. Baselines were randomly allocated at 3,4, or 5 consecutive shifts. Higher scores indicate feeling more appreciated.



Graphs show the participant responses to the item: “How much appreciation do the older adults in your care have for you?” at Baseline (Phase A), Intervention (Phase B) and Follow up (Phase C). Frequency of measurement in Phase A was on a shift by shift basis, and weekly on Phases B & C. Baselines were randomly allocated at 3,4, or 5 consecutive shifts. Higher scores indicate feeling more appreciated.

Appendix O Qualitative Questionnaire Coding Example

Participant

1. What have you noticed about patients' moods and their engagement with activities in the last three months?
   Patients involved in the magic table have engaged well and responded to it appropriately , except for a couple of patients. Their mood improved during interaction and for a short while later.

2. What have you noticed about your relationships with patients in the last three months?

Staff have observed that when patients are involved in activities they respond better to staff interaction . Trust appears to be built

3. What have you noticed about how you carry out your work duties in the last three months?

Nothing - work duties are carried out regardless, however I have tried to incorporate activities and organise time for this around my daily tasks.

4. What have you noticed about how you feel about your work in the last three months?

Nothing, but the magic table has given staff a focus . I always enjoy my work but have been given job satisfaction with the results that the magic table has given and the response from the patients.

5. What have you noticed about your stress levels while at work in the last three months?

Stress levels vary depending on the complex requirements of patients and their degrees of stress and / or distress displayed. Meaningful activities and distraction techniques help alleviate this, even for staff

6. What have you noticed about your satisfaction with work in the last three months?

See question 4 answer
It has been a satisfying part of the magic table project, due to patient response & enjoyment. Both staff and patient have interacted well.