INPLASY PROTOCOL

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None declared.

Is doll therapy an effective intervention for psychological and behavioural symptoms in people with dementia? Systematic review and meta-analysis

Corregidor-Sánchez, AI[1].

Review question / Objective: **To determine the effectiveness of doll therapy in reducing the occurrence of psychological and behavioural symptoms in older people with dementia.**
Condition being studied: **WHO recognises dementia as a public health priority, with the number of people with dementia set to triple by 2050 (WHO | Dementia, n. d.). It is necessary to know which non-pharmacological interventions can ameliorate the symptoms of dementia. In this regard, it has been reported that doll therapy can reduce episodes of agitation and aggression, because it helps people find reasons to communicate and interact, as well as representing a meaningful activity that is part of the caregiving role. However, this therapy is not without ethical dilemmas, as some health professionals and family members consider that this therapy may infantilise the person with dementia. The aim of this review is to understand and quantify the benefits of this therapy on the well-being of people with dementia, in order to contribute to the decision making process on whether or not to use it.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 March 2021 and was last updated on 24 March 2021 (registration number INPLASY202130090).

INTRODUCTION

Review question / Objective: **To determine the effectiveness of doll therapy in reducing the occurrence of psychological and behavioural symptoms in older people with dementia.**

Rationale: **Dementia is a devastating geriatric syndrome, not only because of its increasing incidence (WHO estimates that 10 million new cases are registered each year (Dementia, n. d.) but also because of the great impact of its symptoms on the**

daily life of the person and their relatives/carers). The search for non-pharmacological therapies to maximise the autonomy and well-being of people with dementia and their caregivers has become an urgent social and health care issue. In advanced stages of dementia, the person experiences significant problems that prevent him/her from interacting satisfactorily with his/her environment, causing great suffering. These symptoms may include agitation, physical or verbal aggression and erratic wandering. Doll therapy has been described as a non-pharmacological intervention, based on attachment theory, which may be useful in reducing the presence of these symptoms and generating states of calm and well-being. However, the results obtained in previous systematic reviews (Mitchell et al., 2016; Ng et al., 2017) are inconclusive. This may be because the included studies mostly lacked the necessary methodological rigour, being anecdotal studies. The aim of this meta-analytic review is to review the scientific literature and select studies that meet at least half of the CONSORT statement standards (Schulz et al., 2010) to perform a meta-analysis of all randomised clinical trials that have aimed to explore the effectiveness of doll therapy in people with dementia.

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METHODS

Search strategy: TITLE-ABS-KEY (("lifelike doll" OR "baby doll" OR "doll therapy" OR "baby doll therapy" OR "doll therapy intervention" OR "doll" OR "empathy doll" or กฐreborn baby therapyกฑ or กฐserenity baby for alzheimerกฑ) AND ("Alzheimer Disease" OR "Dementia" OR "alzheimer" OR "alzheimer's" OR "alzheimer dementia" OR "dementia sufferers" AND ("nursing home resident" OR "long term care" OR "cognitive decline" OR "cognitive impairment")).

Participant or population: Persons with dementia.

Intervention: Therapy doll.

Comparator: Comparator or control groups may be groups of people receiving another non-pharmacological technique aimed at calming stages of anxiety or aggression, or groups with no treatment.

Study designs to be included: Two types of studies will be included: 1. Studies for systematic review: Case control, clinical trial, controlled clinical trial, double blind, evidence-based, evidence synthesis, feasibility study, health technology assessment, intervention, longitudinal, multicenter study, pilot, random allocation, randomized controlled trials,, standard of care, treatment outcome. 2. Studies for systematic review and meta-analysis: Randomized controlled trial, randomized studies.

Eligibility criteria: 1. Studies using wrist therapy as an intervention technique. 2. Studies with quantitative data 3. Studies with people over 65 years of age with a diagnosis of dementia.

Information sources: Nine databases (Cochrane Library, Scopus, PEDro, Medline, CSIC, Web of Science, OT Seeker, NGCH and CINAHL).

Main outcome(s): Agitation/aggression, dysphoria/depression, anxiety, irritability/lability, disinhibition, euphoria, apathy/indifference, aberrant motor behavior, sleep and night\time behavior change.

Additional outcome(s): Delusions, hallucinations, appetite/eating disturbances, quality of life.

Data management: Covidence review software will be used for data administration and recording.

Quality assessment / Risk of bias analysis: An independent reviewer will assess the methodological quality of the studies using the items included in RevMan: Random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, and incomplete outcome data (losses to follow-up). They will be categorized as 'high', 'low' or 'unclear' for each of the items.

Strategy of data synthesis: Objective measures for psychological and behavioural symptoms of dementia will be included. Means before and after the intervention will be calculated with their standard deviations (SD). Post-Pre differences will be analysed. The SD of these differences will be calculated by imputation of a correlation coefficient to be found in studies with sufficient information, from the pre and post SD and the SD of the difference. The mean of these coefficients will be calculated (r=0.85) and applied to the rest of the studies. The Hedges standardised mean difference (SMD) adjusted with its 95% confidence interval (95% CI) will be used as a measure of effect size. The overall effect size, weighted by the sample size of the studies, will be calculated using the inverse variance method and a random effects model, using a 95% CI and its statistical significance using the z-test. The effect size will be interpreted using Cohen's criteria for pooled estimates. A value of 0.8 will be considered a large effect. To facilitate clinical interpretation, the pooled MDS from each meta-analysis will be converted to the original scale. This difference will be compared to the smallest clinically important difference to assess the clinical utility of the intervention effect.

Subgroup analysis: The analysis of subgroups will be related to the type of centre in which the intervention takes place (residential homes, day centres, domiciliary).

Sensitivity analysis: After performing the meta-analysis, the influence of each of the studies obtained will be studied. The results of the meta-analysis will be replicated by excluding one of the studies included in the review at each step. If the results thus obtained are similar, both in direction and magnitude of effect and statistical significance, this indicates that the analysis is robust.

Language: English.

Country(ies) involved: Spain.

Keywords: Therapy doll, non-pharmacological therapy, dementia, alzheimer.

Dissemination plans: Upon completion of the review and meta-analysis it is planned to publish the results in journals in the field of geriatrics and dementia.

Contributions of each author:
Author 1 - Ana Isabel Corregidor-Sánchez.