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### Effect of doll therapy in managing challenging behaviors in people with dementia: a systematic review

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# Effect of doll therapy in managing challenging behaviors in people with dementia: a systematic review

## Abstract

**Background:**Challenging behaviors among people with dementia are frequently treated with pharmacological interventions, with antipsychotic medications being the treatment of choice. Concerns with the use of these medications include the risk of mortality, their side effects and their effectiveness in managing the challenging behaviors. Various non-pharmacological approaches have been implemented to manage the challenging behaviors; however there has been no review undertaken to investigate the effects of doll therapy in the management of challenging behaviors among people with dementia.

**Objectives:**The overall objective of this study was to undertake a systematic review of the effects of doll therapy on challenging behaviors (including agitation and verbal or physical aggression) in people with dementia. **Inclusion criteria** **Types of participants:**This review considered studies that included adults (age >18years) diagnosed with dementia and living in a community setting or residential accommodation.

**Types of intervention(s)/phenomena of interest** The intervention of interest was the use of doll therapy compared to pharmacological and or other non-pharmacological interventions. **Types of studies** All randomized, quasi-randomized and cluster randomized controlled trials evaluating the effect of doll therapy in managing challenging behaviors in people with dementia were included in the review. In the absence of randomized controlled trials, cohort, case-control and descriptive studies were included.

**Types of outcomes** The outcomes of interest were changes in challenging behaviors including agitation, verbal and physical aggression, as well as interaction with staff, other patients and residents, activity level and quality of life. **Search strategy** The search aimed to find published and unpublished studies through electronic databases, reference lists, key reports and the World Wide Web. An extensive search was undertaken for the following databases MEDLINE, CINAHL, EMBASE, and the Cochrane Central Register of Controlled Trials. Databases were searched up to February 2014. The search for unpublished studies included: Dissertation Abstracts International, ProQuest Dissertation & Theses and MedNar.

**Methodological quality** Methodological quality was assessed independently by three reviewers using the Joanna Briggs Institute Meta-Analysis of Statistics Assessment and Review Instrument checklists.

**Disagreements** that arose between the reviewers were resolved through discussion. **Data collection**

Quantitative data were extracted from papers included in the review using the standardized data extraction tool from the Joanna Briggs Institute Meta-Analysis of Statistics Assessment and Review Instrument. The data was extracted by one reviewer and checked by a second reviewer. Disagreements that arose between the reviewers were resolved through discussion. All results were subject to double data entry.

**Data synthesis** For this review statistical pooling of the data was not possible due to the heterogeneity of the studies, therefore, the findings are presented in narrative form. **Results** A total of six studies were included in the final review. Of the three studies that investigated the impact of doll therapy on agitation and aggressive behaviors among people with dementia, two reported an improvement in agitation and aggressive behaviors and one reported no statistically significant decrease ( $p=0.07$ ) in aggressive behaviors among residents who used the dolls. In the only study that investigated positive behaviors, statistically significant improvements ( $p< 0.005$ ) in positive behaviors from baseline ( $6.32 \pm 4.13$ ) to the three months follow-up ( $14.21 \pm 9.86$ ) were observed among residents who used the dolls. In addition, an increase in levels of positive activity among residents who used the dolls was reported in two other studies. **Conclusions:**here is limited evidence to support the use of doll therapy for management of agitation and aggress

## Keywords

Dementia, alzheimers, dolls, aggression

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## Disciplines

Medicine and Health Sciences | Social and Behavioral Sciences

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## Effect of doll therapy in managing challenging behaviours in people with dementia: A systematic review

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## Executive summary

### Background

Challenging behaviours among people with dementia are frequently treated with pharmacological interventions with antipsychotic medications being the treatment of choice. Concerns with the use of these medications include the risk of mortality, their side effects and their effectiveness in managing the challenging behaviours. Various non-pharmacological approaches have been implemented to manage the challenging behaviours however there has been no review undertaken to investigate the effects of doll therapy in the management of challenging behaviours among people with dementia.

### Objectives

The overall objective of this study was to undertake a systematic review of the effects of doll therapy on challenging behaviors (including agitation and verbal or physical aggression) in people with dementia.

### Inclusion criteria

#### *Types of participants*

This review considered studies that included adults (age >18years) diagnosed with dementia

and living in a community setting or residential accommodation.

***Types of intervention(s)/phenomena of interest***

The intervention of interest was the use of doll therapy compared to pharmacological and or other non-pharmacological interventions.

***Types of studies***

All randomized, quasi-randomized and cluster randomized controlled trials evaluating the effect of doll therapy in managing challenging behaviours in people with dementia were included in the review. In the absence of randomized controlled trials, cohort, case-control and descriptive studies were included.

***Types of outcomes***

The outcomes of interest were changes in challenging behaviours including agitation, verbal and physical aggression, interaction with staff, other patients and resident, activity level and quality of life.

**Search strategy**

The search aimed to find published and unpublished studies through electronic databases, reference lists, key reports and the World Wide Web. An extensive search was undertaken for the following databases Medline, CINAHL, Scopus, and the Cochrane Central Register of Controlled Trials (CENTRAL).

**Methodological quality**

Methodological quality was assessed independently by three reviewers using the Joanna Briggs Institute Meta-Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI) checklists. Disagreements that arose between the reviewers were resolved through discussion.

**Data collection**

Quantitative data was extracted from papers included in the review using the standardized data extraction tool from JBI-MAStARI. The data was extracted by one reviewer and checked by a second reviewer. Disagreements that arose between the reviewers were resolved through discussion. All results were subject to double data entry.

**Data synthesis**

For this review statistical pooling of the data was not possible due to the heterogeneity of the studies, therefore, the findings are presented in narrative form.

**Results**

A total of six studies were included in the final review. Of the three studies that investigated the impact of doll therapy on agitation and aggressive behaviours among people with dementia, two reported an improvement in agitation and aggressive behaviours and one reported no statistically significant decrease ( $p=0.07$ ) in aggressive behaviours among residents who used the dolls. Statistically significant improvements ( $p< 0.005$ ) in positive behaviours from baseline ( $6.32 \pm 4.13$ ) to the three month follow-up ( $14.21 \pm 9.86$ ) were observed among residents who used the dolls.

## **Conclusions**

There is limited evidence to support the use of doll therapy for management of agitation and aggressive behaviours among people with dementia. This treatment modality however has no side effects and provides a safe comfort measure for people with dementia.

## **Implications for Practice**

The evidence obtained from the review does not provide a concrete base for the development of practice guidelines. Until stronger evidence becomes available, practices relating to doll therapy for the management of agitative and aggressive behaviours among people with dementia will continue to be dictated by local preferences. It is important to be aware of the ethical and practical issues concerning the appropriateness of doll therapy and whether the benefits obtained from doll therapy can justify its use. It is vital that discussions with family members and carers be held prior to the use of doll therapy for people with dementia.

## **Implications for Research**

This review has provided a guide to future priorities for research, firstly the use of more rigorous research designs and the inclusion of validated and reliable outcome measures. Prospective trials in this subject need to be robust and use sample sizes based on power calculations to detect a clinically meaningful difference in order to assist clinicians and policy makers in making informed decisions about the appropriate use of doll therapy for the management of agitative and aggressive behaviours in people with dementia.

## **Keywords**

Dementia, alzheimers, dolls, aggression

# **Introduction**

## **Background**

It is estimated by the year 2050 that 115.6 million people globally will have dementia,<sup>1</sup> the majority of whom will be from the developing countries. Dementia often referred to as a disease, is a process of transition from a healthy, active state to a dependent state with progressive loss of memory, functional skills, and independence.<sup>2</sup> Classic symptoms range from loss of ability to express the right words or to understand what others are saying, personality changes and mood swings and the decline in performing activities of daily living.<sup>3</sup> It has been suggested that over 50% of patients with dementia will experience challenging behaviours<sup>4</sup> which can include agitation, wandering, altered sleeping patterns, disinhibited behaviour which may include inappropriate sexual behaviour and harmful behaviours such as aggression.<sup>5,6</sup>

It has been postulated that people with dementia exhibiting challenging behaviours have some universal emotional needs that are often not fulfilled. These needs include: (1) being needed and feeling useful, (2) to be able to care for others, (3) having an increased sense of self-worth, (4) to love and be loved, and (5) to be able to convey their emotions without inhibition.<sup>7</sup> In clinical practice these challenging behaviours are frequently treated with pharmacological interventions with antipsychotic medications being the treatment of choice.<sup>8,9</sup> Concerns with the use of these medications include the risk of mortality,<sup>10</sup> their side effects and their effectiveness in managing the challenging behaviours.<sup>1,11,12</sup> Extra pyramidal symptoms, falls, gait disturbances, sedation, tardive dyskinesia and cerebrovascular incidents have been widely reported in the literature to be associated with the use of antipsychotics for people with challenging behaviours.<sup>13</sup> Evidence-based guidelines have therefore been developed to advise on the prescribing requirements for these drugs.<sup>14,15</sup> Living with dementia is distressing not only for the patient when they experience the challenging behaviours, but it also has a negative impact on the quality of life of their carers.<sup>16</sup>

#### *Non-pharmacological management of challenging behaviours in patients with dementia*

Given the adverse effects associated with pharmacological management various non-pharmacological approaches have been implemented to address the emotional needs that cause the inappropriate behaviours.<sup>17</sup> These include doll therapy<sup>18</sup>, physical activity programs<sup>19</sup>, music therapy<sup>3</sup>, aromatherapy<sup>20</sup>, massage and touch<sup>21</sup>, and art therapy.<sup>22</sup> Systematic reviews of the literature published in the Cochrane Library have demonstrated reductions in challenging behaviours following the use of physical activity,<sup>19</sup> music therapy<sup>3</sup>, aromatherapy<sup>20</sup>, massage and touch<sup>21</sup>, and art therapy.<sup>22</sup> However there has been no review undertaken to investigate the effects of doll therapy in managing people with challenging behaviours.

#### *Doll therapy*

Doll therapy has been used for patients with dementia for over 20 years and is based on the principles of attachment theory.<sup>23</sup> Although the conceptual work on attachment focussed on children, the impact of attachment experiences persist from childhood into adult life.<sup>24</sup> For people with dementia, attachment behaviour can be observed at various stages of dementia and the presence of parent

fixation or searching for deceased relatives has been reported when attachment needs were not being met.<sup>25</sup>

The use of dolls for therapeutic purposes involves giving a doll to a person with dementia to care for and is purported to assist in overcoming some of the attachment needs.<sup>26</sup> For example cuddling and caring behaviours towards the doll is said to be an expression of being needed, feeling useful and to be able to care for others.<sup>27</sup> In addition, hugging a transitional object such as a doll is a representation of security during a period of uncertainty.

Doll therapy has been reported to reduce agitation, aggression and other challenging behaviours of concern in people with dementia.<sup>18,28</sup> In contrast, doll therapy has been reported by staff and family members to be childish, demeaning, and patronising.<sup>29</sup> Doll therapy as a strategy in managing challenging behaviours in people with dementia has not yet been quantified in a manner to enable clinicians to make an informed decision about its benefits. Therefore the aim of this review was to present the best available evidence relating to the effect of doll therapy in managing challenging behaviours in people with dementia.

## **Objectives**

The objective was to identify the effectiveness of doll therapy on challenging behaviors (including agitation and verbal or physical aggression) in people with dementia.

## **Inclusion criteria**

### ***Types of participants***

This review considered studies that included adults (age >18 years) diagnosed with dementia, living in residential or community settings and demonstrating challenging behaviours. Adults with dementia receiving antipsychotics were also included and analysed separately.

### ***Types of intervention(s)/phenomena of interest***

This review included studies that evaluated the effects of giving a doll to a person with dementia for the management of challenging behaviours. The review included doll therapy delivered by either health professionals or carers. Studies were included irrespective of the number and duration of the doll therapy sessions. Studies were excluded if the approach to giving the doll was not described.

The following comparisons were made:

Doll Therapy vs no intervention

Doll Therapy vs other non-pharmacological interventions

Doll therapy vs pharmacological interventions.

Studies that used other toys such as teddy bears and mechanised pets were excluded.

### ***Types of studies***

All randomized, quasi-randomized, cluster randomized controlled trials and case studies evaluating the effect of doll therapy in managing challenging behaviours in people with dementia were included in the review. In the absence of randomized controlled trials, cohort, case-control and descriptive studies were included.

### ***Types of outcomes***

The primary outcomes of interest were changes in challenging behaviours measured using validated scales or through observation and included:

- Agitation, physical and verbal aggression including swearing, shouting and screaming
- Negative physical behaviours such as excessive pacing, wandering, poorly dressed and poor hygiene
- Negative emotional behaviours such as being tearful, withdrawal depressed, low, upset, anxious

Secondary outcomes included:

- Use of neuroleptics
- Positive behaviours including positive verbalisations, being happy, joyful, content or pleased, bright, tidy and groomed
- Social behaviours including interaction with staff and other patients or residents
- Appropriate activity level including engagement in art, craft, socialising or exercising
- Well being and quality of life
- Staff perceptions of doll use

### **Search strategy**

The search strategy aimed to find both published and unpublished studies. A three-step search strategy was utilized in this review. An initial limited search of MEDLINE and CINAHL was undertaken followed by analysis of the text words contained in the title and abstract, and of the index terms used to describe the article. A second search using all identified keywords and index terms was then undertaken across all included databases. Thirdly, the reference list of all identified reports and articles were searched for additional studies. Studies published until January 2014 in the English language were considered for inclusion in this review. Relevant conference proceedings were searched to identify any further trials or research in progress.

The databases searched included: MEDLINE (1966-2014), CINAHL (1982-2014), EMBASE (1980-current) and the Cochrane Library up to and including 2014 Issue 1. As each database has its

own indexing terms, individual search strategies were developed for each database. During the development of the search strategy, consideration was given to the diverse terminology used and the spelling of keywords as this would influence the identification of relevant studies. The search for unpublished studies included: Dissertation Abstracts International, ProQuest Dissertation & Theses and MedNar.

The keywords used were, Alzheimers, play therapy, doll, toys, alternate therapy. Please refer to Appendix I for search strategies utilized.

## **Method of the review**

Quantitative papers selected for retrieval were assessed by three independent reviewers for methodological validity prior to inclusion in the review using standardized critical appraisal instruments from the Joanna Briggs Institute Meta Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI) (Appendix II). Any disagreements that arose between the reviewers were resolved through discussion, or with a third reviewer.

## **Data collection**

Quantitative data were extracted from papers included in the review using the standardized data extraction tool from JBI-MAStARI (Appendix III). The data extracted included specific details about the interventions, populations, study methods and outcomes of significance to the review question and specific objectives.

## **Data synthesis**

The studies included in the review were largely descriptive hence data could not be pooled in statistical meta-analysis using JBI-MAStARI. A narrative synthesis was therefore undertaken based on the outcomes of interest.

## **Results**

### ***Description of studies***

There were 450 studies identified from the search strategy. Following removal of duplicates, the majority were excluded based on a review of the title and abstract of the citation against the inclusion criteria. A total of 17 studies were deemed potentially eligible for the review and full text was obtained. (Table 1) On further examination eleven trials were excluded as six of them were literature reviews, four were personal experiences and in one trial the data was not available. Six studies were included in the final review. (Figure 1) Appendix IV presents the reasons for why these studies were excluded.



## PRISMA 2009 Flow Diagram

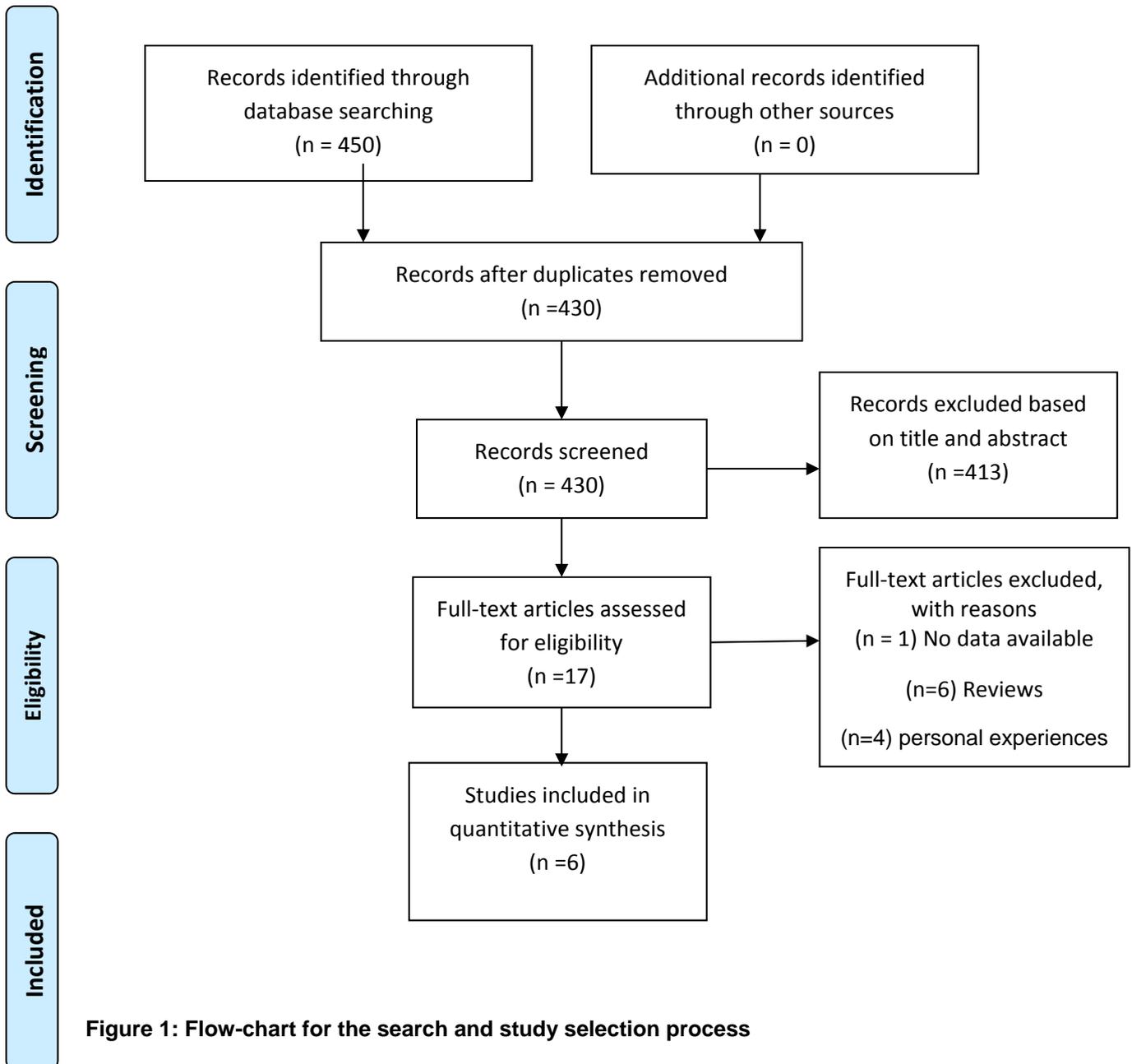


Figure 1: Flow-chart for the search and study selection process

Table 1 Number of studies found and retrieved

Number of studies found	Number selected for retrieval
450	17

Six studies involving a total of 261 participants were included in the final review. (Table 2) The studies were conducted in Australia<sup>27</sup>, United Kingdom<sup>18,30,31</sup>, Scotland<sup>32</sup>, and the USA.<sup>33</sup> The number of participants in the studies ranged from 1<sup>27</sup>- 115.<sup>33</sup> Two studies<sup>30,33</sup> compared the use of dolls to no dolls, two were single arm studies,<sup>18,31</sup> one was a case study,<sup>27</sup> and the final a case series study.<sup>32</sup> The mean age of participants in the studies ranged from 69<sup>33</sup>- 85<sup>30</sup> years. With one exception<sup>27</sup>, all the remaining studies included both genders although in most trials the majority of the participants were female.

## MASTARI

Table 2 Number of studies included and excluded

Number of studies included	Number of studies excluded
6	0

A clear description of the doll therapy intervention was reported in all studies. In one study<sup>32</sup> the therapist walked around the ward carrying the doll or wheeling the doll in a pram and left it with interested residents for one hour /week. In three studies<sup>18,30,31</sup> dolls were introduced by placing them on a table or lounge and residents were free to pick them up and in the study by Green<sup>33</sup> residents were offered a doll. In these four studies residents could interact with the dolls as many times and for as long as they wanted. In the last study the doll was given as a present.<sup>27</sup>

The length of doll therapy varied from one hour /week<sup>32</sup> to having the doll continuously.<sup>27</sup> The types of dolls used were clearly described in all but two studies.<sup>31,33</sup> Provision of information about the study to the families of participants was reported in three studies.<sup>30-32</sup>

### **Methodological quality**

All trial reports were evaluated against the criteria outlined in the methods of the review to assess methodological quality. There was 100% concordance between the reviewers in this respect. Overall, the quality of the studies was low with a mean of four criteria being described. (Table 3)

Three studies<sup>18,32,33</sup> provided a clear description of the included sample. In all studies, participants self selected the use of dolls. The nature of the interventions and the observational method of data collection, precluded blinding of the participants, care provider and assessor in most of the trials.

A wide range of outcome measures were used in the included trials. The effect of doll therapy on agitation, verbal and physical aggression, positive and negative behaviours, activity level, interactions with staff and other residents and mood were measured using an investigator developed prediction and

impact sheet.<sup>18,30</sup> Well being was measured using the Bradford Dementia group Well being profiling tool.<sup>32</sup> Use of neuroleptics was assessed from the medical notes.<sup>30,33</sup> The duration of follow-up for all outcomes ranged from one week to three months after introduction of the doll.

For further descriptions see Summary Tables. (Appendix V)

Table 3 Methodological quality of included studies

Author	Was study based on a random or pseudo-random sample?	Were the criteria for inclusion in the sample clearly defined?	Were confounding factors identified and strategies to deal with them stated?	Were outcomes assessed using objective criteria?	If comparisons are being made, was there a sufficient description of the groups?	Was follow up carried out over a sufficient time period?	Were the outcomes of people who withdrew described and included in the analysis?	Were outcomes measured in a reliable way?	Was appropriate statistical analysis used?
James 2006	No	Yes	Unclear	Yes	N/A	Yes	N/A	Yes	Yes
Minshull 2009	No	Yes	Unclear	Yes	N/A	Yes	N/A	Yes	Unclear
Green 2011	No	Yes	Unclear	Yes	N/A	Yes	N/A	Yes	Yes
Ellingford 2007	No	Unclear	Unclear	No	N/A	Yes	N/A	Yes	Yes
Mackenzie 2006	No	Yes	Unclear	No	N/A	Yes	N/A	No	Unclear
Bisiani 2012	No	No	Unclear	No	N/A	Yes	N/A	No	Unclear

## Results

For this review results have been presented by outcomes.

### Agitation, physical and verbal aggression

Three studies<sup>18,30,31</sup> investigated the impact of doll therapy on agitation and aggressive behaviours among people with dementia. Two single arm studies<sup>18,31</sup> reported an improvement in agitation and aggressive behaviours among those who used a doll<sup>18,31</sup> although, these improvements were not statistically significant. The third study<sup>30</sup> reported statistically significant improvements in aggressive behaviours from baseline to the three month follow-up among those who used a doll ( $p < 0.005$ ) compared to those who did not ( $p = 0.07$ ). However, there were no statistically significant decrease ( $p = 0.07$ ) in aggressive behaviours among residents who used the dolls compared to the non doll users.

<sup>30</sup>

### Negative physical and emotional behaviours

Two studies measured this outcome. One study<sup>30</sup> assessed the impact of using dolls on negative behaviour of residents with dementia. Negative behaviour involved action/activity; negative verbalisations; negative mood state; and negative physical appearance. A statistically significant decrease ( $p < 0.005$ ) in negative behaviours from baseline (Mean:  $13.71 \pm 13.41$ ) to the three month follow-up (Mean:  $8.03 \pm 9.85$ ) were observed among residents who used the dolls. However no statistically significant decrease ( $p = 0.59$ ) in negative behaviours were observed among residents who used the dolls compared to the non doll users. In the second study<sup>27</sup> which was a case study, negative physical behaviours completely eradicated and there was a major reduction in the number and frequency of negative emotional behaviours, and psychosocial behaviours at the seven day follow-up.

### Neuroleptic use

Two studies<sup>30,33</sup> assessed the impact of using dolls on neuroleptic use. In the first study<sup>30</sup> the results indicated that changes in neuroleptic use were made in only 1% of the residents. The second study<sup>33</sup> investigated the use of Haldol for previous negative behaviours (PNB) for patients with and without a doll. Lower average number of unscheduled Haldol doses (0.77 doses) were reported in patients who used dolls ( $n = 22$ ) compared to those who did not use the dolls (2.12 doses).

### Positive behaviours

One study<sup>30</sup> assessed the impact of using dolls on positive behaviour of residents (n=66) with dementia. In this study positive behaviours included action and/or activity; positive verbalisations; positive mood state; and positive physical appearance. Statistically significant improvements ( $p < 0.005$ ) in positive behaviours from baseline ( $6.32 \pm 4.13$ ) to the three month follow-up ( $14.21 \pm 9.86$ ) were observed among residents who used the dolls. Similarly, statistically significant improvements ( $p < 0.005$ ) in positive behaviours were observed among residents who used the dolls compared to the non doll users.

## **Social behaviours**

### *Interacting with staff and other residents*

Two single arm studies<sup>18,31</sup> investigated the impact of doll therapy on interactions with staff. Both studies reported greater levels of interaction with staff and fellow residents following the use of doll therapy.

## **Appropriate activity level**

Two studies<sup>18,31</sup> that investigated the impact of doll therapy on activity level reported an increase in levels of activity among residents who used the dolls.

## **Well being and quality of life**

Three studies<sup>18,31,32</sup> investigated the impact of doll therapy on general well being. The two single arm studies reported an increase in levels of perceived happiness among residents who used the dolls<sup>18,31</sup> and the third study reported significant increases in well being scores from baseline to follow-up among residents who used the dolls.<sup>32</sup> It is unclear if the increases in levels of perceived happiness and well being were significant.

## **Staff perceptions of doll use**

One study<sup>31</sup> assessed the care staff's perception of doll therapy. Forty five of the 46 staff felt that there were clear benefits of using the dolls. Ninety three percent stated that the dolls helped with communicating with the residents. Although some carers thought it was babyish'; 'totally demeaning';

patronising'; 'inappropriate and thought it would confuse residents further'. These results demonstrate that doll therapy presents practical and ethical problems.

Two studies<sup>18,31</sup> reported problems associated with the use of dolls. These included possessiveness, arguments over ownership of the dolls; perceiving the doll to be a baby and carers and family finding it infantilisation and demeaning.

## **Discussion**

This systematic review was undertaken to investigate the effect of doll therapy for the management of challenging behaviours in people with dementia, and has summarized the best available evidence at the time of the report. A systematic literature search resulted in six published studies that were eligible for inclusion in this review. The trials involved both male and female adult patients. The majority of the studies were descriptive studies and the overall reporting of the methods was poor.

Although six studies were included in the review, the results remain inconsistent. This inconsistency could be attributed to the study designs and the methods used to assess outcomes. The lack of RCTs prevented the use of meta-analysis, as a result, this report is mainly in the narrative form. The findings from this systematic review should be interpreted cautiously, given the quality of the included studies.

Three studies<sup>18,30,31</sup> investigated the impact of doll therapy on agitation and aggressive behaviours among people with dementia and the results were inconsistent with two reporting reductions and one reporting no difference in agitative and aggressive behaviours among those who used a doll compared to the non doll users. Although the follow-up period was three months, the measures used to assess the outcomes were non validated tools which reduced the reliability of the results. In addition outcomes were measured by staff who were not blinded to the intervention and the results could therefore be biased based on the attitudes of staff towards doll therapy. The doll users were a self selecting group which is a major bias in all the included studies. The self selection makes it difficult to determine the effect of doll therapy. In addition the research designs and the small sample sizes used in the studies limits the ability to generalise the results.

The review found a significant increase in positive behaviours and a significant decrease in negative behaviours following the use of doll therapy. This could be due to the fact that the behaviours were worded in positive terms, which may have influenced the perceptions of the outcome assessors. The evidence relating to the use of neuroleptics remains inconclusive.

## **Conclusion**

What is clear from this systematic review is that there is limited evidence to support the use of doll therapy for management of agitative and aggressive behaviours among people with dementia.

However, it can be postulated that this treatment modality has no side effects and provides a safe comfort measure for people with dementia. Nevertheless it is important to be aware of the ethical and practical issues concerning the appropriateness of doll therapy and whether the benefits obtained from doll therapy can justify its use. It is vital that discussions with family members and carers be held prior to the use of doll therapy for people with dementia.

### ***Implications for practice***

The evidence obtained from the review does not provide a concrete base for the development of practice guidelines. Until stronger evidence becomes available, practices relating to doll therapy for the management of challenging behaviours among people with dementia will continue to be dictated by local preferences and cost factors.

### ***Implications for research***

This review has provided a guide to future priorities for research, firstly the use of more rigorous research designs and the inclusion of validated and reliable outcome measures. Future work in this area requires assessing the impact of the doll therapy on family members and carers. Prospective trials in this subject need to be robust and use sample sizes based on power calculations to detect a clinically meaningful difference in order to assist clinicians and policy makers in making informed decisions about the appropriate use of doll therapy for the management of challenging behaviours in people with dementia.

### ***Conflict of Interest***

None

### **Acknowledgements**

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## Appendix I: Search strategy

### MEDLINE

Search ID#	Search Terms
S1	(MH "Dementia+")
S2	TX (dement* OR BSPD)
S3	TX Alzheimer*
S4	TX (creutzfeldt* OR jcd OR cjd)
S5	TX (Kohlsch* OR "amelo-cerebro-hypohidrot*" OR "amelo cerebro hypohidrot*" OR aphasia* OR frontotemporal* OR Huntington* OR (Kluver* N2 Bucy*) OR (Diffuse Neurofibrillar* N4 calcification*))
S6	TX (Lewy* N2 bod*)
S7	TX (Pick* N2 diseases*)
S8	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7
S9	(MH "Therapeutics+")
S10	(MH "Drug Therapy+")
S11	(MH "Complementary Therapies+")
S12	(MH "Psychotherapy+")
S13	TX (intervention* OR therap* OR treatment*)
S14	TX (drug OR pharmacolog*)
S15	TX (alternative OR "non pharmacolog*" OR "non-pharmacolog*")
S16	TX psychotherap*
S17	S13 AND S14

S18	(S13 AND S15) OR S16
S19	( S9 OR S18 OR S11) NOT ( S10 OR S17 )
S20	S10 OR S17
S21	TX (doll OR dolls OR dolly OR dollies)
S22	(MH "Play Therapy")
S23	TX "Play Therap**"
S24	S22 OR S23
S25	(PT "Clinical Trial") OR (PT "randomized controlled trial")
S26	(MH "Cluster Analysis+")
S27	(MH "Prospective Studies+")
S28	(MH "Case-Control Studies+")
S29	TX ("randomi* control* stud**" OR "randomi* control* trial**" OR "randomi* stud**" OR "randomi* trial**")
S30	S25 OR S29
S31	TX ("quasi randomi**" OR "quasi-randomi**" OR "quasi experiment**" OR "quasi-experiment**")
S32	S31
S33	TX ("clustered trial**" OR "clustered stud**" OR ((cluster* OR group* OR place) AND ("randomi* control* stud**" OR "randomi* control* trial**" OR "randomi* stud**" OR "randomi* trial**"))
S34	(S25 AND S26) OR S33
S35	TX (("prospective" AND "cohort**") OR ("retrospective" AND "cohort**"))
S36	S27 OR S35
S37	TX ("case control**" OR "case-control**")

S38	S28 OR S37
S39	TX ("descriptive research*" OR "descriptive stud*")
S40	S39
S41	S8 AND S21 AND S30
S42	S8 AND S21 AND S32
S43	S8 AND S21 AND S34
S44	S8 AND S21 AND S36
S45	S8 AND S21 AND S38
S46	S8 AND S21 AND S40
S47	(S8 AND S30) NOT S9
S48	(S8 AND S32) NOT S9
S49	(S8 AND S34) NOT S9
S50	(S8 AND S36) NOT S9
S51	(S8 AND S38) NOT S9
S52	(S8 AND S40) NOT S9
S53	S8 AND S20 AND S30
S54	S8 AND S20 AND S32
S55	S8 AND S20 AND S34
S56	S8 AND S20 AND S36
S57	S8 AND S20 AND S38
S58	S8 AND S20 AND S40

S59	S8 AND S19 AND S30
S60	S8 AND S19 AND S32
S61	S8 AND S19 AND S34
S62	S8 AND S19 AND S36
S63	S8 AND S19 AND S38
S64	S8 AND S19 AND S40
S65	S8 AND (S30 OR S32 OR S34)
S66	S8 AND (S36 OR S38 OR S40)
S67	S8 AND S21
S68	S41 OR S42 OR S43
S69	S44 OR S45 OR S46
S70	S47 OR S48 OR S49
S71	S50 OR S51 OR S52
S72	S53 OR S54 OR S55
S73	S56 OR S57 OR S58
S74	S59 OR S60 OR S61
S75	S62 OR S63 OR S64
S76	(MH "Geriatrics")
S77	TX (gerontolog* OR geriatr*)
S78	S76 OR S77
S79	S21 AND S78

**CINAHL**

Search ID#	Search Terms
S1	(MH "Dementia+")
S2	TX (dement* OR BSPD)
S3	TX Alzheimer*
S4	TX (creutzfeldt* OR jcd OR cjd)
S5	TX (Kohlsch* OR "amelo-cerebro-hypohidrot*" OR "amelo cerebro hypohidrot*")
S6	TX (Lewy* N2 bod*)
S7	TX (Pick* N2 diseas*)
S8	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7
S9	(MH "Therapeutics+")
S10	(MH "Drug Therapy+")
S11	(MH "Alternative Therapies+")
S12	(MH "Psychotherapy+")
S13	TX (intervention* OR therap* OR treatment*)
S14	TX (drug OR pharmacolog*)
S15	TX (alternative OR "non pharmacolog*" OR "non-pharmacolog*")
S16	TX psychotherap*
S17	S13 AND S14
S18	(S13 AND S15) OR S16
S19	( S9 OR S18 OR S11) NOT ( S10 OR S17 )

S20	S10 OR S17
S21	TX (doll OR dolls OR dolly OR dollies)
S22	(MH "Play Therapy")
S23	TX "Play Therap*"
S24	S22 OR S23
S25	(MH "Clinical Trials+")
S26	(MH "Quasi-Experimental Studies+")
S27	(MH "Cluster Sample+")
S28	(MH "Prospective Studies+")
S29	(MH "Case Control Studies+")
S30	(MH "Descriptive Research")
S31	TX ("randomi* control* stud*" OR "randomi* control* trial*" OR "randomi* stud*" OR "randomi* trial*")
S32	S25 OR S31
S33	TX ("quasi randomi*" OR "quasi-randomi*" OR "quasi experiment*" OR "quasi-experiment*")
S34	S26 OR S33
S35	TX ("clustered trial*" OR "clustered stud*" OR ((cluster* OR group* OR place) AND ("randomi* control* stud*" OR "randomi* control* trial*" OR "randomi* stud*" OR "randomi* trial*"))
S36	(S25 AND S27) OR S35
S37	TX (("prospective" AND "cohort*") OR ("retrospective" AND "cohort*"))
S38	S28 OR S37
S39	TX ("case control*" OR "case-control*")

S40	S29 OR S39
S41	TX ("descriptive research*" OR "descriptive stud*")
S42	S30 OR S41
S43	S8 AND S21 AND S32
S44	S8 AND S21 AND S34
S45	S8 AND S21 AND S36
S46	S8 AND S21 AND S38
S47	S8 AND S21 AND S40
S48	S8 AND S21 AND S42
S49	(S8 AND S32) NOT S9
S50	(S8 AND S34) NOT S9
S51	(S8 AND S36) NOT S9
S52	(S8 AND S38) NOT S9
S53	(S8 AND S40) NOT S9
S54	(S8 AND S42) NOT S9
S55	S8 AND S20 AND S32
S56	S8 AND S20 AND S34
S57	S8 AND S20 AND S36
S58	S8 AND S20 AND S38
S59	S8 AND S20 AND S40
S60	S8 AND S20 AND S42

S61	S8 AND S19 AND S32
S62	S8 AND S19 AND S34
S63	S8 AND S19 AND S36
S64	S8 AND S19 AND S38
S65	S8 AND S19 AND S40
S66	S8 AND S19 AND S42
S67	S8 AND (S32 OR S34 OR S36)
S68	S8 AND (S38 OR S40 OR S42)
S69	S8 AND S21
S70	S43 OR S44 OR S45
S71	S46 OR S47 OR S48
S72	S49 OR S50 OR S51
S73	S52 OR S53 OR S54
S74	S55 OR S56 OR S57
S75	S58 OR S59 OR S60
S76	S61 OR S62 OR S63
S77	S64 OR S65 OR S66
S78	(MH "Gerontologic Care") OR (MH "Gerontologic Nursing+") OR (MH "Geriatrics")
S79	TX (gerontolog* OR geriatr*)
S80	S78 OR S79
S81	S21 AND S80

## **Cochrane Library**

<b>ID</b>	<b>Search Hits</b>
#1	MeSH descriptor: [Dementia] explode all trees
#2	dement* or BSPD
#3	Alzheimer*
#4	creutzfeldt* or jcd or cjd
#5	Kohlsch* or "amelo-cerebro-hypohidrot*" or "amelo cerebro hypohidrot*" or aphasia* or frontotemporal* or Huntington* or (Kluver* N2 Bucy*) or (Diffuse Neurofibrillar* N4 calcification*)
#6	Lewy* N2 bod*
#7	Pick* N2 diseas*
#8	#1 or #2 or #3 or #4 or #5 or #6 or #7
#9	MeSH descriptor: [Therapeutics] explode all trees
#10	MeSH descriptor: [Drug Therapy] explode all trees
#11	MeSH descriptor: [Complementary Therapies] explode all trees
#12	MeSH descriptor: [Psychotherapy] explode all trees
#13	intervention* or therap* or treatment*
#14	drug or pharmacolog*
#15	alternative or "non pharmacolog*" or "non-pharmacolog**"
#16	psychotherap*
#17	#13 and #14
#18	(#13 and #15) or #16
#19	(#9 or #18 or #11) not (#10 or #17)
#20	#10 or #17
#21	doll or dolls or dolly or dollies
#22	MeSH descriptor: [Play Therapy] this term only
#23	Play Therapy
#24	#22 or #23
#25	MeSH descriptor: [Clinical Trial] explode all trees
#26	MeSH descriptor: [Cluster Analysis] explode all trees
#27	MeSH descriptor: [Prospective Studies] explode all trees
#28	MeSH descriptor: [Case-Control Studies] explode all trees
#29	"randomi* control* stud*" or "randomi* control* trial*" or "randomi* stud*" or "randomi* trial**"
#30	#25 or #29
#31	"quasi randomi*" or "quasi-randomi*" or "quasi experiment*" or "quasi-experiment**"
#32	#31
#33	"clustered trial*" or "clustered stud*" or ((cluster* or group* or place) and ("randomi* control* stud*" or "randomi* control* trial*" or "randomi* stud*" or "randomi* trial**"))
#34	(#25 and #26) or #33
#35	("prospective" and "cohort*") or ("retrospective" and "cohort*")
#36	#27 or #35
#37	"case control*" or "case-control**"
#38	#28 or #37
#39	"descriptive research*" or "descriptive stud**"

## **Appendix II: Appraisal instruments**

**MAStARI Appraisal instrument**

**JBI Critical Appraisal Checklist for Descriptive / Case Series**

Reviewer ..... Date .....

Author ..... Year ..... Record Number .....

	Yes	No	Unclear	Not Applicable
1. Was study based on a random or pseudo-random sample?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Were the criteria for inclusion in the sample clearly defined?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Were confounding factors identified and strategies to deal with them stated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Were outcomes assessed using objective criteria?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. If comparisons are being made, was there sufficient descriptions of the groups?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Was follow up carried out over a sufficient time period?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Were the outcomes of people who withdrew described and included in the analysis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Were outcomes measured in a reliable way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Was appropriate statistical analysis used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Overall appraisal:    Include             Exclude             Seek further info

Comments (Including reason for exclusion)

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## **Appendix III: Data extraction instruments**

**MAStARI data extraction instrument**

**JBI Data Extraction Form for  
Experimental / Observational Studies**

Reviewer ..... Date .....

Author ..... Year .....

Journal ..... Record Number .....

**Study Method**

RCT                       Quasi-RCT                       Longitudinal   
Retrospective                       Observational                       Other

**Participants**

Setting \_\_\_\_\_

Population \_\_\_\_\_

**Sample size**

Group A \_\_\_\_\_ Group B \_\_\_\_\_

**Interventions**

Intervention A \_\_\_\_\_

Intervention B \_\_\_\_\_

Authors Conclusions:  
\_\_\_\_\_  
\_\_\_\_\_

Reviewers Conclusions:  
\_\_\_\_\_  
\_\_\_\_\_

**Study results**

**Dichotomous data**

<b>Outcome</b>	<b>Intervention ( ) number / total number</b>	<b>Intervention ( ) number / total number</b>

**Continuous data**

<b>Outcome</b>	<b>Intervention ( ) number / total number</b>	<b>Intervention ( ) number / total number</b>

## Appendix IV: Excluded studies

Andrew A. The ethics of using dolls and soft toys in dementia care. *Nursing & Residential Care* 2006;8:419-21.

**Reason for exclusion: Review paper.**

Mitchell G, O'Donnell H. The therapeutic use of doll therapy in dementia. *British Journal of Nursing* 2013;22:329.

**Reason for exclusion: Review paper.**

Verity J. Dolls in dementia care bridging the divide. *Australian Journal of Dementia Care* 2006;14:25-7.

**Reason for exclusion: Review paper.**

James I, Reichelt F, Morse R, Mackenzie L, Mukaetova-Ladinska E. The therapeutic use of dolls in dementia care. *Journal of Dementia Care* 2005;13:19-21.

**Reason for exclusion: Review paper.**

Mackenzie L, Wood-Mitchell A, James I. Thinking about dolls. *J Dement Care* 2006;14:16-7.

**Reason for exclusion: Review paper.**

Higgins P. Using dolls to enhance the wellbeing of people with dementia in residential care. *Nurs Times* 2010;106:18-20.

**Reason for exclusion: Review paper.**

Ehrenfeld M, Bergman R. The therapeutic use of dolls. *Perspectives in psychiatric care* 1995;31:21-2.

**Reason for exclusion: Personal experience.**

Gibson S. A personal experience of successful doll therapy. *Australian Journal of Dementia Care* 2005;13:22.

**Reason for exclusion: Personal experience.**

Godfrey S. Doll Therapy. *Australian Journal on Ageing* 1994;13:46.

**Reason for exclusion: Personal experience.**

Stevenson A. Dolls: handle with care. *Journal of Dementia Care* 2010;18:16-7.

**Reason for exclusion: Personal experience.**

Tamura T, Nakajima K, Nambu M, et al. Baby dolls as therapeutic tools for severe dementia patients. *Gerontechnology* 2001;1:111-8.

**Reason for exclusion: Data not available**

**Appendix V: List of study findings / Conclusions**

**MAStARI**

<b>Study</b>	<b>Methods</b>	<b>Participants</b>	<b>Intervention</b>	<b>Study Findings/Conclusions</b>	<b>Notes</b>
James et al 2006 UK	Descriptive Study	33 elderly residents with dementia living in a social care home  <b>Mean age</b> 83.5 years  <b>Gender M/F</b> 2/11	Doll therapy (n=13) Dolls were introduced into homes. Residents were free to pick a doll.	<b>3 months follow up</b>  <i>Appropriate activity level</i> Mean- 4.06 (0.57)  <i>Interacting with staff</i> Mean 4.38 (0.53)  <i>Interacting with other residents</i> Mean 4.25 (0.66)  <i>Happier/Content</i> Mean 4.35 (0.57)  <i>Agitation</i> Mean 3.47 (0.67) Overall increase in levels of activity, interacting with staff, interacting with other residents, happier/content and reduction in agitation at the three month follow up.  <b>Comments from staff members</b> <i>Positive-</i> Interacted with the dolls as if they were babies (mothering) Decreased Isolation  <i>Negative-</i> Possessiveness and arguments over ownership. Relatives were critical	<b>Types of Dolls</b> Life like dolls Staff not instructed to behave in any structured way except to respond positively.  <b>Outcomes assessed by</b> A member of Newcastle Challenging Behaviour Service (NCBS) monitored the interactions with the help of two staff members from the home  <b>Outcomes assessment instrument</b> Prediction sheet and impact sheets designed by the Research and development department of the NCBS Data collected using 1-5 Likert scale, indicating levels of; activity, agitation, perceived happiness and interaction with others. Impact sheets were completed in weeks 1,2,3,8 and 12 (post-trial)
Green et al 2011	Descriptive Study	All patients admitted to a 21	Each patient admitted to the	<b>3 months follow up</b>	<b>Type of dolls</b> Nil description

Study	Methods	Participants	Intervention	Study Findings/Conclusions	Notes
USA		<p>bed geropsychiatric unit with dementia during study and displayed negative behaviours. (N=115)</p> <p><b>Gender M/F</b> 43/72</p> <p><b>Mean age</b> 69 years</p>	<p>unit was ordered a doll in keeping with his or her ethnic racial background.</p> <p><b>Intervention Group</b> Doll Therapy (n=22)</p> <p><b>Control group-</b> No dolls (n=3)</p>	<p><b>Average number of PRN haldol doses</b></p> <p><i>Intervention Group</i> 0.77</p> <p><i>Control Group</i> 2.12</p>	<p>Observation of negative behaviours (agitation, aggression, excessive pacing, wandering) were recorded in a log book along with doll use and PRN haloperidol (haldol) doses.</p>
Ellingford etal 2007 UK	Retrospective audit	<p>66 participants living in 4 residential care homes</p> <p><b>Mean age-</b> 84.41 (8.16)</p>	<p><b>Intervention Group</b> Doll Therapy (n=34)</p> <p>Dolls were introduced to the residents indirectly, such as being place on chairs or small tables in communal areas. Allowed residents to observe and select dolls as they desired</p> <p><b>Control group-</b> No dolls (n=32)</p>	<p><b>3 months follow up</b></p> <p><b>Positive Behaviour</b></p> <p><i>Intervention Group</i> Pre- 6.32 (4.13) Post- 14.21 (9.86) P= &lt;0.005</p> <p><i>Control Group</i> Pre- 7.31 (5.64) Post 7.19 (8.13) P=0.39</p> <p>Difference between intervention and control group at follow up P=0.005</p> <p><b>Negative Behaviour</b></p> <p><i>Intervention Group</i> Pre- 13.71 (13.42) Post- 8.03 (9.85) P=0.005</p>	<p><b>Type of dolls</b> Dolls were all plastic with a soft torso, 16-20 inches in length, eyes that could be open and shut, and no additional auditory or kinetic functions, such as crying or breathing</p> <p><b>Outcomes assessed by</b> Researcher and psychologist extracted from daily communication sheets</p> <p><b>Outcome assessment instrument</b> A keyword data sheet, developed by the investigators based on behaviours reported by staff.</p> <p><i>Behaviour targeted</i> 1. Positive- 4 subcategories;</p>

Study	Methods	Participants	Intervention	Study Findings/Conclusions	Notes
				<p><i>Control Group</i> Pre- 8.97 (12.75) Post 8.50 (12.97) P=0.40</p> <p>Difference between intervention and control groups P=&lt;0.59</p> <p><b>3. Aggression</b> <i>Intervention Group</i> Pre- 1.29 (2.11) Post- 0.32 (0.77) P= 0.005</p> <p><i>Control Group</i> Pre- 0.50 (1.16) Post 0.72 (1.53) P=0.07</p> <p>Difference between intervention and control groups negative P=&lt;0.52</p> <p><b>4. Use of neuroleptics</b> Few changes made to neuroleptic use</p>	<p>Action/activity (engagement in art, craft, socialising or exercising) Positive verbalisations (positive feedback statement or reminiscence) Positive mood state (being happy, joyful, content or pleased) Positive appearance (bright, tidy and groomed)</p> <p>2. Negative - 4 subcategories Action/activity (physical aggression towards people and objects, wandering, non-compliance and self isolation) Negative Verbalisation (verbal aggression, swearing, shouting and screaming) Negative mood state (depressed, low, upset, anxious and agitated) Negative physical appearance (poorly dressed and poor hygiene)</p>
Minsbull 2009 Scotland	Case Series	9 participants from The Royal Edinburgh Rotational Occupational Patients Service	Doll Therapy (n=6) The researcher walked around with the doll and stopped if someone showed interest. The session was carried out for one hour on a weekly	<p><b>1 Month Follow Up</b></p> <p><i>General wellbeing</i> Significant increase in well being scores from baseline to follow up</p> <p><i>Comments from nurses</i> Improved speech and communication</p>	<p><b>Outcomes assessed-</b> The Bradford Dementia group Well Being Profiling tool</p> <p><b>Outcomes assessed by</b> Researcher</p> <p><b>Type of Doll</b> Dolls were taken from an American company Lee Middleton that had open eyes</p>

Study	Methods	Participants	Intervention	Study Findings/Conclusions	Notes
			basis		at all times and did not cry. Weighted to feel like a real baby
Bisiani and Angus  2012 Australia	Single Case Study	Single female participant	Doll Therapy (n=1)  The doll was presented as a gift to the subject in her bedroom	Reduction in behaviours of concern related to the need for attachment and a considerable decline in levels of anxiety and agitation. Extensive ongoing improvement in social interaction and communication.	<b>Type of Doll</b> Culturally appropriate, made of silicone, texture & appearance similar to human skin, eyes that closed and lifelike hair & eyelashes. Dressed in typical baby clothes with cloth cap & booties  <b>Outcomes assessed by</b> Care staff recording in the adjusted ACFI behavioural tool Use of field observations with care staff
Mackenzie et al  UK  2006	Descriptive study	46 care staff and 14 key workers working in two Elderly Mentally Ill (EMI) homes.  <b>Gender M/F</b> 2/12	Fourteen dolls were introduced into the homes by placing them on a table in the lounge area. Residents were free to 'pick them up' from the table	<u>Care Staff perceptions</u> (n=46) 45/46 carers felt that there were clear benefits of using the dolls which included reduction in wandering, improvement in intimate-care interactions (bathing etc.) and an improvement in speech.  16 carers (35%) reported that there had been some problems using the dolls: arguments between residents over ownership of dolls, residents trying to feed their dolls and dolls being mislaid.  <u>Key workers perceptions</u> (n=14) Residents tended to be more active, showed greater levels of interaction with staff and fellow residents, appeared happier, less agitated and more amenable to personal-care activities.	<b>Types of Dolls</b> Nil description  <b>Outcomes assessed by</b> The researcher assessed outcomes after 3 weeks using questionnaire,

