

Fidelity challenges while implementing an intervention aimed at increasing eating performance among nursing home residents with cognitive decline: a multicentre, qualitative descriptive study design

Running head: Interventions implementation fidelity in nursing home

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Conflicts of Interest Statement

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The datasets analysed during the current study are available from the corresponding author upon reasonable request

Abstract

Aims and objectives: To increase the knowledge on fidelity challenges in intervention studies promoting eating independence in residents with cognitive decline living in Nursing Homes (NH).

Background: A few studies have documented to date factors affecting fidelity in intervention studies **performed** in NH settings. Moreover, fidelity issues in intervention studies aimed at promoting eating independence among NH residents with cognitive decline have not been **studied** to date.

Design: A hybrid study design was performed in 2018 and reported here according to the COnsolidated criteria for REporting Qualitative research.

Methods: In a clustered multicentre before/after intervention study design, a nested, **multicentre** qualitative descriptive design was performed. Four researchers with a nursing background, who received appropriate training, implemented the designed intervention. This consisted in intentional rounds in the dining rooms during lunchtime and was based on supportive, prescriptive, and informative prompts delivered to residents with cognitive decline **aimed at stimulating eating independence**. A momentary assessment method was used, based on daily diary **filled in** by participant researchers after every session of intervention delivery on the following five dimensions of fidelity: (a) adherence, (b) dose (or exposure), (c) intervention quality, (d) participant responsiveness, and (e) program differentiation. A direct content analysis of the narratives reported on the diaries was performed.

Results: Factors increasing or hindering intervention fidelity during **its implementation** emerged at the NH, staff, family caregivers, resident, researchers and at the intervention **itself** levels.

Conclusions: Several factors emerged and all **reported** potentially both positive and negative influences on fidelity while implementing an intervention aimed at promoting eating independence among NH residents. Fidelity challenges should be considered as dynamic in NH intervention studies, where continuous adjustments of the intervention delivered are required.

Relevance to clinical practice: A calm environment, with staff members showing a caring behaviour, and researchers having achieved good familiarity with the NH setting, the residents, their family carers and the staff members, can all increase intervention fidelity.

Keywords: Fidelity; Intervention Studies; Nursing Home; Narratives; Qualitative Descriptive; Self-Feeding; Eating Performance; Cognitive decline; Dementia; Residents.

Impact statement

- Due to the increased needs of older individuals living in Nursing Homes (NHs) with cognitive decline and the lack of available research, studies **in this field have been identified as a** priority, specifically aimed at evaluating the effectiveness of interventions improving independence in eating.
- No evidence on the measurement of fidelity challenges in intervention studies aimed at increasing and/or maintaining eating performance among NH residents with cognitive decline has been documented to date.
- Factors increasing or hindering fidelity while an intervention **aimed at improving eating independence is implemented**, emerged at the NH, staff, family caregivers, resident, researchers and at the intervention itself levels.
- **All factors emerged can** potentially have both positive and negative effects on fidelity and **should be considered in future research** protocols for intervention studies as elements affecting fidelity, thus deserving continuous evaluation.

1 | INTRODUCTION

Based on the increased needs of older individuals living in Nursing Homes (NHs) especially with cognitive decline and dementia, and the lack of available evidence, studies in this field have recently become a priority, specifically in regards to how to promote eating independence (Keller, Beck, & Namasivayam, 2015). Ensuring independent eating as long as possible increases quality of life (QoL), well-being, and prevents malnutrition, dehydration, and several adverse outcomes (e.g., pressure sores, pneumonia) that can lead to an increased risk of mortality (Abbott et al., 2013; Bunn et al., 2016). However, among reviews available summarising the effectiveness of interventions (Abbott et al., 2013; Aselage, 2010; Aselage & Amella, 2010; Aselage, Amella, & Watson, 2011; Bunn et al., 2016; Chang & Roberts, 2008; Chang & Roberts, 2011; Douglas & Lawrence, 2015; Hanson, Ersek, Gilliam, & Carey, 2011; Liu, Cheon, & Thomas, 2014; Liu, Galik, Boltz, Nahm, & Resnick, 2015; Manthorpe & Watson, 2003; Watson, 1994; Watson & Green, 2006), only two have provided information regarding fidelity challenges. Specifically, Liu et al. (2014) and Liu et al. (2015) discussed the evaluation of the intervention integrity, according to the Quality Assessment Tool for Quantitative Studies. Moreover, in providing recommendations, Liu et al. (2015) suggested that future **educational** programmes and mealtime assistance interventions of residents with dementia, implemented by trained researchers, should also involve nursing caregivers to evaluate the fidelity of the intervention's implementation in real-world settings.

Fidelity is the degree at which the intervention under investigation has been implemented as planned, thus supporting the validity of the conclusions regarding the association between the intervention and the outcomes measured (Ibrahim & Sidani, 2016). Its measurement has been considered as part of the implementation research (Peters, Adam, Alonge, Agyepong, & Tran, 2013). Moreover, fidelity measures have been underlined as being important to support the generalisation of a given intervention under study to other settings or populations (Bellg et al., 2004; Carroll et al., 2007; Dusenbury, Branningan, Falco, & Hansen, 2003; Resnick et al., 2005; Ibrahim & Sidani, 2016).

Although different across disciplines, frameworks available on fidelity measurements are based on five dimensions or elements: (a) the degree of adherence to an intervention as compared to that expected, (b) its dose (or exposure), (c) its quality, as delivered, (d) the responsiveness in terms of how participant(s) respond to or are engaged by an intervention, and (e) the programme differentiation as to which elements of the interventions are essential (Bellg et al., 2004; Carroll et al., 2007; Dusenbury et al., 2003; Resnick et al., 2005; Ibrahim & Sidani, 2016). Neglecting to address these dimensions or elements has been shown to increase the risk of type I and type II errors (Bellg et al., 2004), thereby limiting the scientific confidence about the effectiveness of the intervention and the likelihood to obtain the same outcomes while implementing the intervention in practice. Moreover, neglecting to measure fidelity affects the quality of the research methodology used thus leading to poor studies, ultimately affecting the strength of the evidence **found** (Bellg et al., 2004).

Given the lack of studies measuring fidelity to date, and its recognised relevance in evidence development (Bova et al., 2017; Ibrahim & Sidani, 2016), the aim of this study was to improve knowledge on fidelity challenges in NHs' intervention studies aimed at promoting eating independence among residents with cognitive decline **or** dementia.

2 | BACKGROUND

Measuring fidelity has been documented as an increased challenge in palliative care, public health and in NH settings (Simpson et al., 2018). In these contexts, studies are often based on complex interventional frameworks where fidelity is difficult to measure (Carroll et al., 2007; Craig et al., 2013). Moreover, some researchers have put more emphasis on theoretical levels of fidelity, assessing the degree of consistency between the intervention's active ingredients and its components and activities as theoretically identified, and less attention to the operational levels of fidelity as the concrete measure of the degree to which the intervention is delivered according to that established in the research protocol (Sidani & Braden, 2011). Other researchers have instead put more emphasis on empirical levels, measuring some fidelity elements (e.g., the degree of adherence to a designed

intervention, dose, delivery quality) and neglecting others, such as participants responsiveness and interventions differentiation (Dane & Schneider, 1998) mainly because measuring fidelity is itself a complex process (Resnick et al., 2005).

Theoretical studies available aimed at discussing intervention fidelity in NH settings (Sidani & Braden, 2011), have underlined that these **settings** should be considered as complex adaptive systems composed of several variables such as staff, residents, family caregivers, their background, training, expectations, and needs. Each of these variables has unpredictable freedom of action **with effects on the intervention delivered** often interconnected to each other (Simpson et al., 2013). For example, an aggressive response during lunchtime might affect eating performances and the nutritional intake of other residents eating in the same dining room. Moreover, each NH should be considered based on its own history (e.g., social, physical), requiring continuous internal adjustment in a way that cannot be controlled by researchers when ensuring intervention fidelity (Jordan et al., 2009; Simpson et al., 2013). Consequently, intervention fidelity can vary across facilities and inside of the same facility when multicentre studies are performed (Appelhof et al., 2018).

Among the empirical studies available, some internal NH's organisational factors, such as the lack of human resources or their inexperience with the setting (e.g., novice nurses or moved from one unit to another), the high turnover rates and the organisational changes, have been all investigated as preventing fidelity. The culture of the unit, as barriers to change influenced by the background of the health care professionals, the lack of proficiency in language in the case of foreign staff and some well-established routines, have all been proven to prevent fidelity. Conversely, an effective leadership capable of promoting changes and the full involvement of the staff in educational and multidisciplinary meetings have been reported to positively affect fidelity. Some external variables, such as the status of the NH (public vs. private) have also been reported to influence fidelity (e.g., Jordan et al., 2009; Simpson et al., 2013).

Alongside the above-mentioned factors that have been set at the NH level, some other factors have been documented at the research protocol and at the research team levels (Simpson et al., 2013).

Among the first, fidelity has been shown to be affected by the lack of familiarity of the staff with the research methods (Simpson et al., 2013), as well as **by** the fatigue experienced by both staff and **residents** due to **research** involvement. **For example, older individuals** often have symptoms, such as pain or fatigue, that can threaten their involvement in a prolonged research process. The poor compliance from the staff, the inflexibility of some routines overlapping with new interventions under investigation (Simpson et al., 2013), together with the potential role of ‘*gatekeepers*’ of families, can also generate obstacles in fidelity (Simpson et al., 2013). The NH residents and staff are in need of continuously adapted interventions based on how they respond. However, only a few studies to date have investigated the fidelity in these so-called ‘*adaptive studies*’ (Hanson et al., 2011; Zarit, Lee, Barrineau, Whitlatch, & Femia, 2013).

3 | METHODS

3.1 | Aims

To document the challenges affecting fidelity while implementing an intervention aimed at promoting eating independence in residents with cognitive decline **or** dementia living in NHs. Specifically, the research question was the following: What factors affect fidelity in an intervention study promoting eating independence among residents with cognitive decline/dementia living in NHs?

3.2 | Study design and rationale

A hybrid study design based on two focuses aimed at testing the effects of an intervention on given outcomes, while observing and documenting information on intervention implementation (Curran, Bauer, Mittman, Pyne, & Stetler, 2012) was performed. The study design was decided according to its dual focus that has been documented to speed up the translation of knowledge into practice (Curran et al., 2012). Specifically,

- (a) the primary study was a multicentre clustered before/after intervention study and it was performed in 2018;

(b) in the context of the primary study, a nested qualitative **multicentre** descriptive design (Sandelowski, 2000) was conducted according to its ability to (i) gain all in-depth elements of implementation fidelity (Zarit et al., 2013); and (ii) use the knowledge developed by researchers on the basis of their time spent in complex adaptive contexts such as NHs (Simpson et al., 2013). **Figure 1 summarises the primary and nested study in their main phases. Moreover, the study has been here reported** according to the COnsolidated criteria for REporting Qualitative research (Tong, Sainsbury, & Craig, 2007), as shown in the Supplementary Table 1.

3.3 | Primary study: brief presentation of the intervention study

In the context of a large research project including all 105 NHs existing in a region located in the North of Italy (Palese et al., 2018), a primary intervention study was carried out involving four public NHs offering an homogenous amount of nursing care by Nursing Aides (NAs) and Registered Nurses (RNs) for approximately 75 minutes/day/resident. Residents were admitted in these NHs with moderate to severe functional dependence due to different health conditions—mainly cognitive decline or dementia (hereafter cognitive decline, given that not always a diagnosis was recorded in the medical records; Palese et al., 2018).

Based on the increased responsiveness of individuals with cognitive decline to environmental stimuli, which can trigger confusion, agitation, aggressiveness and an increased dependence in daily living activities (Fleming, Goodenough, Low, Chenoweth, & Brodaty, 2016; Sloane et al., 2002), the involved NHs were **firstly** assessed in their therapeutic principles with the Therapeutic Environment Screening Survey for Nursing Home (TESSH-NH) (Sloane et al., 2002). Thus, the **following** intervention **study** was conducted in different NH environments, with poor, moderate, good and excellent TESSH-NH scores, respectively (Palese et al., 2020).

The aim of the primary study was to assess the effectiveness of an intervention on eating independence among residents living in NHs. The study was designed in three phases: (a) the before

or pre-intervention phase (three weeks in duration), (b) the intervention phase, including the intervention delivery (two weeks), and (c) the after phase, or follow-up (one week). All phases included only residents eating in the dining room of the facility as identified with the inclusion criteria reported in Table 1.

According to the evidence available (Liu et al., 2014), before, during and after the intervention delivery, the following outcomes were assessed: (a) eating performance by using the Edinburgh Feeding Evaluation in Dementia scale (EdFED) (Watson, 1993); (b) proportion of meal and liquids assumed during lunch; (c) time required to complete the meal (in minutes); and (d) occurrence of adverse events (e.g., agitation, leaving the dining room).

In the intervention phase, one researcher in each NH not involved in nursing care, and who was already familiar with residents, the staff and the environment because involved since the pre-intervention phase, implemented the intervention (Bellg et al., 2004) during each lunch period for 14 days. The intervention was based on the following elements (a) rounding crossing all residents at need of support in eating by passing and staying for a while seated in the table where they were sitting in a group of four; (b) looking into the eyes of the resident at higher need of support, call her/him by name and if pleasing, touch her/him on the shoulder, or hug them; and (c) delivering non-pressing and positive-tone prompts (Table 1) initially to the residents at higher need, and then to those with less pressing needs and sitting around the table.

A total of 140 residents were eligible: according to the inclusion criteria, 107 residents were included with an average age of 87.27 (SD 1.25), mainly female (84; 78%). The average Barthel Index score was 14.19 (SD 8.69) indicating a higher degree of functional dependence (0: totally dependent, 100: totally independent; Mahoney & Barthel, 1965). At the Cognitive Performance Scale, they reported an average score of 3.75 (SD 0.79; from 0 to 6, intact to severe impairment, respectively; scores ≥ 4 represented moderate/severe impairment; Morris et al., 1994).

3.4 | Nested qualitative descriptive study: Aims

In the context of the primary study, a nested qualitative study was performed aimed at emerging factors affecting fidelity while implementing the intervention designed to promote eating independence.

3.4.1 | Participants

The four researchers who implemented the intervention were all eligible. They were invited by the Principal Investigator to participate in reporting factors affecting fidelity according to their experience and they agreed to the proposal. They were in their final stage of their nursing education, all female, from 23 to 26 years old, and trained to implement the intervention.

3.4.2 | Data collection process

A momentary assessment method based on diaries was used, which allowed the collection of multiple data to minimise bias and generate in-depth self-reflections (Janssens, Bos, Rosmalen, Wichers, & Riese, 2018) on implementation fidelity challenges as experienced by researchers. As per Janssens et al. (2018) and Stone and Shiffman (2002), daily data collection was performed for the entire period of the intervention implementation, by asking participant researchers to answer some questions, in a calm room in the NH, just after each meal ended. Specifically, two forms of reflections to measure fidelity were adopted: the ‘*in action*’ and ‘*on action*’ reflections (Schon, 1984). The ‘*in action*’ or the ‘*here-and-now*’ reflections were reported daily in the diary, while for the ‘*on action*’ reflections, participant researchers were invited to perform in-depth, retrospective reflections (Janssens et al., 2018) on the entire process of intervention implementation, at the end of the study. The guiding questions answered in each page of the diary are reported in Table 2.

On the first day, the diary was completed by each researcher and the Principal Investigator. They were both present in the dining room when the participant researcher delivered the intervention: therefore, with the aim of minimizing missed reflections they discussed and filled in the diary together. In the following days, each participant researcher was invited to report her reflection,

individually. The Principal Investigator stimulated periodical feedbacks regarding the ongoing process of diary competition. In the middle of the intervention phase, the diaries were supervised to give feedback and encourage reflection on all **dimensions** under investigation. This supervision was performed by the Principal Investigator with each participant researcher in the NH setting, with an open and non-judgmental approach (Jordan et al., 2009). The diary was then kept by participant researchers to complete the ‘on action reflection’ (Schon, 1984) as a global in-depth, retrospective reflection on the entire intervention study and finally sent to the Principal Investigator 15 days after the end of the study.

3.4.3 | Data analysis

The existing fidelity framework, composed of five dimensions (Bellg et al., 2004; Carroll et al., 2007; Dusenbury, Branningan, Falco, & Hansen, 2003; Resnick et al., 2005; Ibrahim & Sidani, 2016) was used as the basis of the questions reported in the diary aimed at triggering self-reflection. Therefore, a direct content analysis (Graneheim & Lundman, 2018) of the narratives reported to each question was performed as an *a priori* plan of analysis (Milles, Huberman, & Saldana, 2014; Stone & Shiffman, 2002). The entire process was conducted by two researchers (AP, BA) and supervised by other two researchers (MH, RW).

Initially, the ‘on action’ and the ‘in action’ narratives were checked for their readability and completeness and numbered progressively (e.g., **Nursing Home, diary number 1, D1**). Then, both were carefully read and re-read, (a) longitudinally (each diary, all narratives regarding all questions) and then (b) horizontally (all diaries, by reading the narratives for the same question). Consequently, factors reported to either positively or negatively influence each dimension of fidelity were extracted initially independently, and then established on the basis of the consensus reached amongst researchers. Thus, a description of each factor was provided also through discussion between researchers. The emerged factors were then organised in the conceptual framework of fidelity

(Sandelowski, 2000) by reporting their influence in both directions, as hindering or promoting fidelity. Strategies to ensure rigor for the entire research process have been reported in Table 3.

3.5 | Ethics considerations

With regards to the primary study, appropriate authorization to access residents, facilities and data were ensured by the health care trust responsible of the facilities (prot. N. 66935, 2017), by the Regional Ethical Committee - XXXXXX., XXXX (prot. N. 29747, 2018) and by the University Internal Review Board (prot. N. 047/2019). For the nested qualitative study, participant researchers were informed of the study aims and procedures; they agreed to function with a double role, in implementing the intervention and in observing factors affecting its fidelity. After a full explanation of the study aims, they gave their written informed consent to participate. Confidentiality of participants researchers and facilities was ensured by anonymising the diaries. Moreover, all residents and their family caregivers were informed with regards to the presence of the researchers, their aims and their role, on an individual basis by the PI (Alvisa Palese); similarly, members of staff were informed. In the dining rooms, informative leaflets on the aims of the ongoing study project were available.

Each participant researcher, after having filled in the diary on a daily basis in a calm and protected room identified in the NH, kept the diary confidential. At the end of data collection, the diaries were sent to the Principal Investigator in a safe manner. Then, diaries were numbered in a blinded fashion to protect the privacy of both the researchers and the NHs where the study was performed.

4 | RESULTS

Different factors affecting intervention fidelity in its dimensions emerged at different levels: some have emerged as promoting while other as hindering fidelity, as reported in Table 4.

4.1 | Factors at the NH level

At the NH level, the characteristics of the environment, such as chaotic and confused versus calm, silent or relaxed, have mainly affected the quality of the intervention delivered and the responsiveness of residents. The pressure manifested by the staff to quickly end the meal processes hindered the ability of researchers to ensure intervention delivery, its dose **and quality with respect to** the designed intervention. The time pressure has also been perceived by residents, reducing their responsiveness to the intervention.

4.2 | Factors at the staff level

Due to the lack of staff members engaged in mealtime, researchers were involved in the care of residents instead of implementing the designed **intervention**. Moreover, the professional competence of **the** staff, in terms of caring versus compensatory behaviour, also affected fidelity. When the staff provided a caring approach, researchers reported increased fidelity in all dimensions; on the other hand, compensatory staff's behaviour prevented fidelity when, for example, the staff physically helped residents to eat, without allowing researchers to implement the **designed** intervention. Furthermore, poor care at the dyad level, namely between the health care provider and the resident – **were reported** to threaten the resident's intervention responsiveness. Similarly, it was reported that staff-to-staff tensions **when not appropriately addressed** prevented intervention-responsiveness among residents.

4.3 | Factors at the family caregivers' level

Primarily, negative interferences were observed at the family caregivers' level; **specifically**, fidelity increased in all dimensions when the relatives were not present during mealtime. In contrast, intervention implementation, dose and quality were all threatened when caregivers were present

because of their direct role in the entire process of mealtime and because of their extensive role with regards to residents sitting at the same table.

4.4 | Factors at the resident's level

Several factors affecting fidelity also emerged at the resident level, where some daily variations in concentration, tiredness and disorientation were all reported as affecting the majority of fidelity dimensions. On the other hand, emerging clinical problems or mood variations, causing bed rest, have been shown to prevent the delivery of the intervention as expected.

Furthermore, a cluster of reactions towards the intervention performed by researchers was reported, from acceptance, which increased all fidelity dimensions, to negative escalation reactions, such as irritation, verbal or non-verbal refusal, aggressive behaviour or leaving the table. These reactions influenced other residents in two different directions: When negative reactions occurred (e.g., aggressive behaviour), residents sitting at the same table were all influenced, and the intervention fidelity became more challenging in all dimensions; in contrast, by witnessing the prompts given by the researcher, some residents mirrored these interventions by stimulating residents sitting around the table to eat and drink independently, thus increasing fidelity in terms of dose.

4.5 | Factors at the researcher level

At the research level, the degree of familiarity with the resident was reported to be crucial in increasing fidelity: knowing the resident and his/her preferences, and manifesting trust in his/her abilities, were all elements that allowed a tailored intervention based on the needs and the daily variations, all increased different dimensions of fidelity. Being present in the setting, researchers also influenced the staff members' behaviour, by influencing their practices by offering good examples of interventions that in turn increased fidelity. However, in some circumstances, misunderstandings regarding the researcher's role and her presence in the dining room caused staff members to detach from mealtime. The resulting increased workloads for the researchers, due to the lack of staff

available or the implicit delegation received by NAs to provide eating care, all threatened the intervention's fidelity with regards to adherence, dose, and implementation quality.

4.6 | Factors at the intervention level

According to the narratives, the essential element of the intervention was represented by supportive prompts that **were reported to increase** all dimensions of fidelity. **Prescriptive and** informative prompts were instead perceived as essential to residents with concentration difficulties and space/time disorientation, **and with a higher degree of cognitive decline**, because of their role in guiding them during the eating task and in increasing responsiveness. Moreover, the posture of the researcher delivering the intervention was reported essential and capable of increasing the quality of the intervention and responsiveness, as staying and sitting for a while, close to and at the same level as the resident.

5 | DISCUSSION

We performed a qualitative study design aimed at detecting factors that **can** hinder and increase fidelity in a study promoting eating independence among NH residents with cognitive decline. To the best of our knowledge, this is the first study exploring factors affecting fidelity in the **NH settings**, while implementing interventions aimed at increasing eating performances in residents with cognitive decline. Moreover, the study was aimed to measure all dimensions of fidelity by assessing also the participants' responsiveness and the programme differentiation, given that only a few studies have considered these elements of fidelity to date (Carroll et al., 2007; Dusenbury et al., 2003).

Nursing homes have been defined as complex adaptive systems, thus non-linear organizational systems, in which several factors or agents interact with each other and where individuals mutually adjust their behaviour with the aim of continuously coping with the internal and external environmental demands. In this context, fidelity issues are extremely difficult to be detected

and documented; moreover, measuring fidelity in “no-one-size-fits all” interventions (Jordan et al., 2009) such as an intervention promoting **eating** independence, constitutes a major challenge given that the implementation might vary from one person to the other (Zarit et al., 2013).

As compared to available NH studies on fidelity, where researchers have documented the relevance of the setting, the research protocol and the team (Simpson et al., 2013), a richer set of factors have emerged **in our study** that have only, in part, been previously documented. According to the findings, all dimensions of fidelity (Bellg et al., 2004; Carroll et al., 2007; Dusenbury et al., 2003; Resnick et al., 2005; Ibrahim & Sidani, 2016), can be affected while implementing an intervention **in a NH setting**.

The environment of NHs can affect fidelity in terms of the quality of the intervention delivered and the resident’s responsiveness. The quality of the NH environment **has not been documented by** Simpson et al. (2013), but previous studies highlighted that the facility environment embodying certain therapeutic principles (reduced noises, appropriate tactile and visual stimuli) can maximise physical, cognitive and other abilities of individuals with cognitive decline (e.g., de Boer et al., 2018; Sloane et al., 2002), while a poor environment can result in excessive functional dependence, thus affecting the resident’s responsiveness to the intervention. The quality of the intervention delivered was also hindered by the NH environment threatening the researcher’s concentration required to conduct and implement the **designed** intervention.

Most of the fidelity dimensions were also affected by time constraints. Simpson et al. (2013) reported that the competing clinical demands on staff can affect the intervention dose, while Liu, Tripp-Reimer, Williams, & Shaw (2018) specifically mentioned **time** pressure as affecting the quality of care delivered to optimise eating performance. However, in our findings, time pressure mainly triggered staff to inappropriately feed **residents before** their actual need to be physically helped; as a consequence, researchers were not given the required opportunity to deliver the designed **interventions because residents were physically helped**.

The limited amount of staff available, instead, shifted the role of researchers from implementing the intervention under investigation to taking care of residents. In conducting NH studies, researchers can experience moral distress in the case of several unmet residents' needs, as the researchers have a supernumerary role and are not involved in the care processes. Alongside the number of staff members, also their competence can influence fidelity in two distinct directions—as a complementary synergistic contribution, thus increasing fidelity in the majority of its dimensions when based on caring behaviour or, in contrast, to hinder attempts performed by researchers in delivering the intervention, as in the case of poor or compensatory care when they unnecessarily physically help residents to eat (the so called 'exceeded care'; McGillivray & Marland, 1999). While the lack of staff and limited time can trigger compensatory care, poor care or inappropriately addressed intra-staff tensions can promote stress and burnout (Costello, Walsh, Cooper, & Livingston, 2018) that can in turn affect negatively the entire quality of care. With regards to these and other critical factors raising ethical considerations (e.g., hurried meals), future studies should consider also these issues in the process of NH recruitment with the purpose of conducting researches in ethically sound environments. There is also a need to consider what kind of support to offer to researchers in these contexts when they witness practices raising ethical issues and how to promote changes in the practice by sharing critical examples with staff, with the purpose of stimulating self-reflection and awareness.

Family caregivers as 'gatekeepers' have been already documented (Simpson et al., 2013). Also in our study, caregivers hindered intervention fidelity in multiple circumstances towards their loved ones and towards other residents sitting around the table. Caregivers' presence has been documented as being challenging during meal times when they do not adhere with staff recommendations (e.g., by helping with eating when not necessary) or when they trigger tension (e.g., when they are in a hurry, stressing the resident during mealtimes) (Palese et al., 2018). The role of the family members has emerged as complex because of their need to keep control over care, by monitoring the care received, providing feedback and compensating for perceived gaps. Moreover,

they live the difficult transition of relinquishing their own responsibility for the loved one's well-being and giving the responsibility to the NH staff. Therefore, to increase fidelity without altering family presence, which has been largely documented as beneficial for residents (Palese et al., 2020), it is strongly suggested to involve the family at the beginning of each intervention study.

At the residents' level, several issues due to cognitive decline (e.g., difficulty in concentration, **tiredness**), as well as mood changes or comorbidities requiring bed rest or hospitalisation, have been shown to affect fidelity. Moreover, the intervention delivered has been documented as generating different **behavioural** responses, most of them negative and following a sort of escalation, which also affects other residents. This seems to confirm that there is a continuous need to adapt the intervention according to the increased sensitivity of individuals with cognitive decline, as excessive demands can trigger confusion, agitation and aggressiveness (de Boer et al., 2018; Fleming et al., 2016; Liu et al., 2014; Sloane et al., 2002).

Interestingly, residents witnessing and mirroring the prompts delivered by researchers, have been reported to perform the same in favour of other residents. Previously, Aselage et al. (2010) reported that when individuals with varying levels of dementia ate together, the person with relatively milder dementia became the caregiver for those with severe dementia. However, the imitation of interventions might also have been influenced by the researcher's familiarity with residents and the NH setting, a factor that has been reported to increase fidelity in most of its dimensions. Previously, Simpson et al. (2013) highlighted the importance of the researchers' familiarity on study integrity.

Changes in daily practice of NAs due to a sort of influence provided by witnessing good examples of care as delivered by researchers also increased fidelity. In contrast, fidelity has been threatened because staff members were found to be detached from the research process and their attempt to fully delegate the task of providing eating care to researchers. A strong NH staff involvement in the study process is not always easy considering a high turnover rate often reported in these contexts (Simpson et al., 2013) thus requiring continuous reinforcement.

Supportive prompts (Heron, 2001) have been reported as essential elements of the intervention and their positive influence was perceived during the entire study process. However, prescriptive and informative prompts were shown to be essential for residents with a higher degree of cognitive decline. Previous studies in the field have reported that Montessori and/or space retrieval methods (e.g., Lin, Huang, Watson, Wu, & Lee, 2011), where each eating task is broken down, shown and described, are effective. Moreover, the researchers' posture (sitting near, in contact with eyes), was also considered an essential part of the intervention, increasing the quality of the intervention's delivery and responsiveness. This posture can be considered a concrete form of a person-centred **approach** (Collecchia, 2019) fully perceived by residents, suggesting that other forms of care, symbolising a hierarchical relationship (standing up in front of the sitting down resident) should be avoided to prevent issues in fidelity.

5.1 | Limitations

The study is affected by several limitations. Firstly, according to the **hybrid design framework** used (Curran et al., 2012) while implementing the intervention, researchers were invited to continuously ensure its fidelity, for example limiting prompts in residents with aggressive behaviour. Therefore, findings reflect a process where strategies aimed at ensuring a greater fidelity have been performed. Secondly, researchers were not involved in the daily care of the residents and they were not members of staff. Therefore, their presence in each NH might have changed the dynamic of normal mealtimes and, consequently, the measurement of fidelity. Similarly, the presence of the Principal Investigator, although not intrusive and occasional, might have affected the fidelity issues encountered by researchers by influencing the mealtime routines. Along this line, although participant researchers have been engaged in the entire study, aimed at developing familiarity with the context and with residents, their presence might have affected the responsiveness and other elements of fidelity.

Thirdly, for what concerns the intervention, a pilot phase was performed before its implementation aiming at assessing its real-world feasibility; moreover, despite the homogeneity of the NHs involved in terms of residents needs and staff, these were different in terms of the quality of the environments as measured with the **TESS-NH** (Palese et al., 2020): all these elements might have **increased** or hindered some fidelity dimensions and their measurement.

Fourth, narratives were collected from researchers involved in the implementation process, and although they have been trained and supervised, findings could have been affected by several factors, as for example: (a) they scrutinised fidelity issues individually, by using a diary, therefore at risk of over or under emphasizing certain factors **or missing others** (Di Giulio & Saiani, 2018); (b) any external validity measure (e.g., a second researcher) has been used to check if the data emerged through the reflection time was authentic; and (c) their preconceptions and their adaptation process in the context due to their long engagement in the same NH, **can all** have introduced biases. Therefore, factors that emerged should be further studied in different NH settings and countries by also involving staff members, residents and family caregivers. However, according to the aim of the primary study, which was to evaluate the intervention effectiveness in dining room settings, the emerged factors affecting fidelity should be considered with caution in their generalisability to interventions performed at the individual levels, e.g., at the bedside.

Finally, only a limited amount of NHs have been involved for a short time, suggesting that future studies evaluating fidelity issues in this context should be conducted on a large scale of for a prolonged period.

6 | CONCLUSION

Several factors can potentially have both positive and negative influences on intervention fidelity. In addition to the complexity of the residents' daily variations and their responses to the intervention delivered, factors emerged at the NH and at the research levels. From the NH point of view, the quality of the environment, the competence and the availability of the staff, as well as the

role played by family caregivers could all affect fidelity. From the point of view of the research process, the researchers' familiarity with the residents and the intervention delivered could also affect fidelity.

Fidelity factors likely to emerge during implementation should be included and monitored in future research protocols. Therefore, future multicentre studies, also at the international **levels** are required to cumulate evidence in this field. Once a certain stability of the evidence will be achieved, factors affecting fidelity should be converted into a check list and a self-reflection guide for researchers performing intervention studies in NHs. Moreover, designing strategies to effectively manage factors affecting fidelity and scrutinising their effectiveness in preventing such issues, is strongly recommended.

7 | RELEVANCE TO CLINICAL PRACTICE

A calm environment, with staff members capable of caring behaviour, where researchers have achieved good familiarity with the setting, the residents, their family carers and the staff members, can increase intervention fidelity. On the contrary, intervention fidelity can be hindered in NHs with a poor environment, limited and untrained resources, time pressures, delivering poor care or with staff members that attempt to delegate meal tasks to researchers. Therefore, an early evaluation of the quality of the NHs' features, as well as extensive engagement of its staff members and family carers are suggested, ensuring also a long engagement of researchers aimed to promote familiarity with the entire micro-world of the NH and *vice versa*.

However, NH environments are not always perfect. Modifying their features exclusively for research purposes and imposing a forced change—assuming this is possible and ethically acceptable—aimed at ensuring a certain degree of stability over time, can theoretically ensure a perfect fidelity, but in-depth threatening the sustainability of the intervention under study, as well as its generalisability. Therefore, factors affecting fidelity should be considered as being dynamic among NH intervention studies, where continuous adjustments are required.

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TABLE 1 Brief description of the primary study

Strategies ensured before study commencement

- (a) Each NH gave their authorisation to be a part of the study;
- (b) The researcher protocol was presented to the head of each unit and to the staff members. The researcher was introduced to the residents and his/her presence explained in the reasons;
- (c) The family caregivers were also informed regarding the presence of the researcher during the entire study, as well as the interventions performed.
- (d) The intervention based upon an extensive revision of the literature (Palese et al., 2020) was piloted and discussed in its elements with nurses working in NHs.

Strategies ensured before starting the intervention implementation

- Identify residents who had greater difficulty and who were used to eat alone (EdFED ≥ 2 ; Watson, 1993);
- Plan a fluid intentional rounding crossing all residents with the above-mentioned needs, to offer a systematic round by passing and staying seated in the table where resident(s) in need are eating;
- When approaching the table, stay and sit for a while, close to and at the same level as the resident; look into the eyes of the resident, call her/him by name and if pleasing, touch her/him on the shoulder, in the back to embrace;
- Generate non-pressing and positive-tone prompts among those reported below.

Prompts According to Heron (2001)

Prescriptive	Give suggestions, recommendations <i>Examples:</i> “Please, drink some water, it’s good to try to taste these potatoes that I think are good...” “Try and know me to say”
Informative	Give information about what is happening or what has just happened; or try to breakdown actions into simple tasks <i>Examples:</i> “These are your potatoes”, “This is your fork” “Here is your meal, I see that there is a soup...”
Supportive	Affirm the value or the outcomes achieved <i>Examples</i> “Brava Mrs. Maria...” “You ate everything...”, “Congratulations!” “It’s almost over... then we have coffee... Do you want some coffee?”

In giving these prompts, also consider other residents eating at the same table that can have higher **eating** performance but who may need support/help.

EdFED: Edinburgh Feeding Evaluation in Dementia (Watson & Green, 2006), *NH*: nursing home

TABLE 2 Guide for the self-reflection diary

Please, report your reflections regarding the following aspects (Carroll et al., 2007)

- 1) Daily, as a reflection '*in action*' (Schon, 1984)
 - (a) Adherence (=a program service or intervention is being delivered as it was designed or written): Were you able to deliver the intervention today as designed in the research protocol? What were the factors that facilitated and hindered the implementation as expected?
 - (b) Exposure or dose (=amount of an intervention received by participants): What were the factors that facilitated or hindered the implementation of the dose of the intervention received by the participants today as compared to that expected by the protocol?
 - (c) Quality of the intervention delivery (=as the manner in which the researcher has delivered the intervention): What are the factors either positively or negatively that have influenced the delivery of the intervention in its quality today?
 - (d) Responsiveness (=how participants respond to the intervention or the degree of engagement that you perceived among residents regarding the intervention): What was the reaction of the residents today? How did they respond to your intervention? Were they engaged in receiving the intervention? What were factors that promoted or hindered their responsiveness today?
 - 2) At the end of the implementation phase, as a reflection '*on action*' (Schon, 1984)
 - (e) Intervention differentiation (=unique features of different components or programs, as well as which elements of the intervention were essential, thus, if absent, the intervention will not have its intended effect): What elements of the interventions were essential (if absent, the intervention would have no effect) according to your whole experience?
-

TABLE 3 Strategies adopted to ensure rigor in the data analysis

Standards (Graneheim & Lundman, 2004)	How standards were ensured
Objectivity (confirmability) as relative neutrality and reasonable freedom from researcher bias	<ul style="list-style-type: none">- The study procedures, as well as the data collection methods and analysis, were described in detail- Personal assumptions were shared between researchers before data analysis- The presence of the Principal Investigator in some occasions, was gentle and non-intrusive, in order to prevent any bias- Diaries were available until the end of the analysis
Dependability (reliability or auditability) as the consistency in procedures across participants over time through various methods	<ul style="list-style-type: none">- Diaries contained questions consistent with the fidelity framework (Carroll et al., 2007)- Pre-printed diaries were homogeneous across NHs (e.g., with the same questions, in the same order)- Expert researchers were involved in the data analysis; only one among them was a novice researcher- The a priori guide for data analysis containing the list of elements comprised in the fidelity framework (Carroll et al., 2007) was provided- All participants were external to the staff of the NH and not involved in the care of residents
Credibility (internal validity) as the truth value of data	<ul style="list-style-type: none">- Factors emerged were supported by quotes as extracted from the diaries- Findings were linked with the fidelity framework (Carroll et al., 2007)

TABLE 4 Factors affecting fidelity dimensions while implementing an intervention promoting **eating independence**

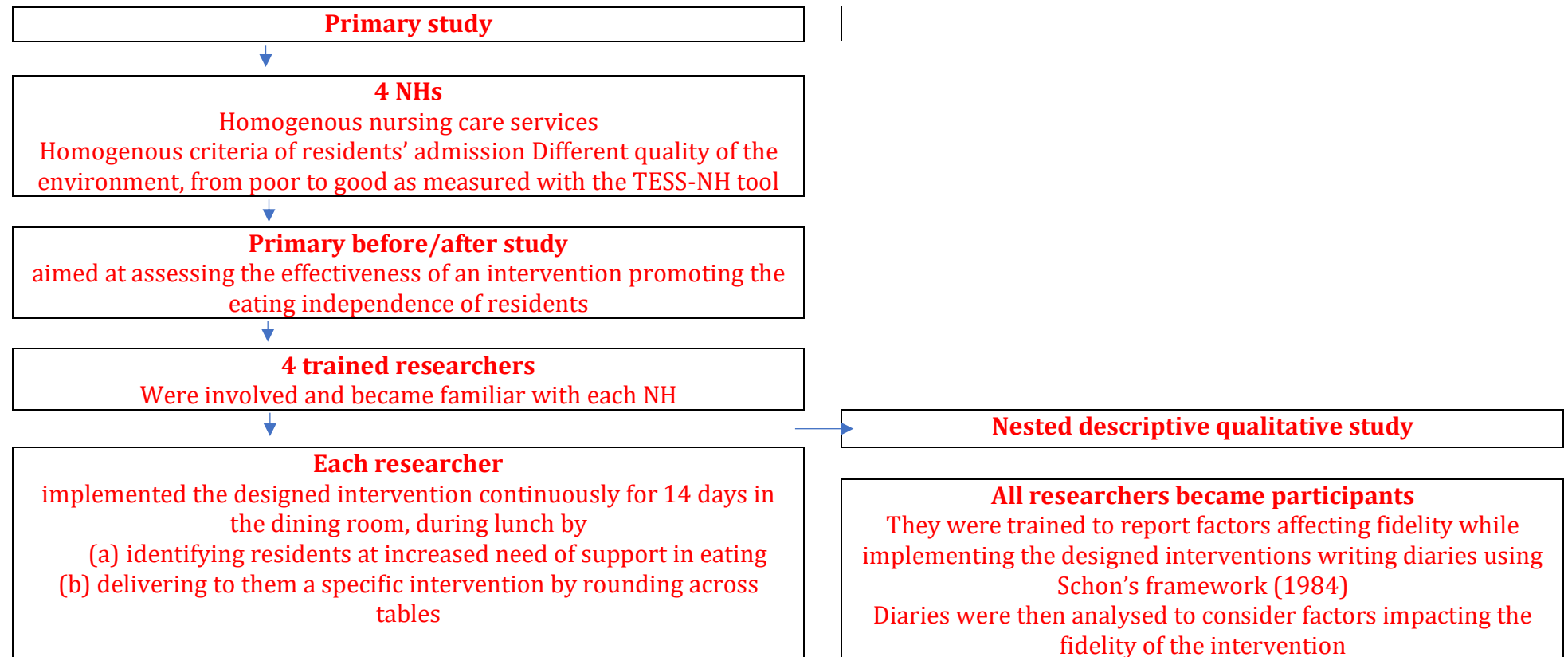
			Fidelity dimensions					
Fidelity challenges: levels	Factors	Description	Adherence	Exposure or dose	Intervention delivery quality	Responsiveness	Intervention differentiation	Quotes
NH	Environment	Chaotic, Confused			↓	↓		“.. The television was distracting all today...” (D1) “The dining room was too crowded today by family caregivers... HCAs...me...” (D2) “Today the environment was confusing, affecting the quality of the intervention” (D4)
	Work processes	Time pressure	↓	↓	↓	↓		“Even today there was a considerable willingness of HCAs to feed residents to accelerate the timing...thus given that they immediately feed the residents, I cannot apply my interventions” (D4) “... there was a tendency to generate pressure to end the meal procedures in a shorter time” (D3)
Staff	Staff available	Limited resources	↓	↓	↓			“the amount of staff was limited today” (D2) “... I was implicitly obliged to help residents comprising my interventions given that no one [staff] was in the dining room to help them (D3)
	Professional competence	Caring behaviour	↑	↑	↑	↑		“...residents were open to my prompts today because it was present that HCA ... with special manners to care for” (D1)
		Compensatory behaviour	↓	↓	↓			“...Although she had started eating independently, seeing that she was slow, the HCA began to feed...(D1) “...she [HCA] began to feed... “(D2; D3; D4)
		Poor care				↓		“...Today there was an HCA who... made some residents angry. This happened also some days ago...” (D1)
	Relationship among staff	Tensions				↓		“Upon my arrival today, there was tension among the staff; they were late in setting the tables and residents perceived that it was because of something negative” (D1; D2)
Family caregivers	Interferences	Absent	↑	↑	↑	↑		“ .. She [the caregiver] was not present ... thus today it was possible to deliver the intervention” (D4)
		Directive	↓	↓	↓			“Due to the strong presence of a caregiver who directed the entire process, it was difficult to deliver the intervention today...” (D2)
		Extensive	↓	↓	↓			“From the second course, a caregiver has feed another resident sitting in the table near his loved one, thus threatening the delivery of my intervention” (D3)
Resident	Daily variations	Clinical issues	↓	↓				“...Today she was ill, she remained in bed” (D1; D3; D4) “I found difficulty today in prompting because of the deafness of the lady...” “lauding my voice means to disturb other residents” (D2)
		Mood disturbances	↓	↓		↓		“She was not in the right mood today...to receive my prompts.” (D2) “he decided not to come in the dining room today, it was not a good day...” (D3)
		Lack of concentration	↓	↓	↓	↓		“she was unfocused during the meal, I sit near to prompt but... my presence increased her distraction given that she will to talk with me...” (D1; D4)

		Somnolence	↓	↓	↓	↓	“She was very tired ...” “During the meal she tended to fall asleep” (D1; D2; D3; D4)	
		Disorientation	↓	↓	↓	↓	“...disoriented on space and time... (D2)	
	Reactions to intervention performed by researchers	Acceptance	↑	↑	↑	↑	“... she accepted the prompts...” (D2) “... there were more prompts accepted regarding liquids instead of meals...today” (D1; D2; D3)	
		Irritated	↓	↓	↓	↓	“.. She tended to get irritated with my prompts...” (D4)	
		Refuse verbally/non-verbally	↓	↓	↓	↓	“.. he refused my prompts...” (D1) “...she refused to answer me, and to look at me when I approached...” (D1; D3) “...she sends me away” (D4)	
		Aggressive	↓	↓	↓	↓	“...she became aggressive when I approached and prompted to eat...” (D1; D2; D3; D4)	
		Leave the table	↓	↓	↓	↓	“.. She abandoned the dining room after 10 minutes...of my intervention delivery...” (D2; D3)	
		Resident-to-residents’ influences	Contamination		↑			“...when I was near another table, a resident has encouraged another resident to eat, ... thus in some ways delivering the interventions instead of me” (D2; D3)
	Disturbing behaviour		↓	↓	↓	↓	“...today she has laughed with her neighbours and annoys ladies who were sitting next to her and this affected their responsiveness to the intervention...” (D3) “...she was agitated today, thus, all residents were disturbed, and prompts were difficult to deliver (D1; D4)	
Researchers	Familiarity	Knowing the resident		↑	↑	↑	“...I have personalised prompts because I know each of them...” (D4; D3; D1)	
		Manifesting trust			↑	↑	“It has been essential to establish a kind of bond and trust with the resident...” (D2)	
		Ensuring a presence	↑	↑		↑	“...They felt considered and I favoured the intervention implementation...” (D2)	
		Tailoring continuously	↑	↑		↑	“...I delivered interventions on most of the residents in the first days, then I focused more and more on a narrower group of them on the basis of their needs” (D1)	
	Research-to-staff relationship	Contamination		↑			“My interventions have tended today to influence staff...they have started to mirror my interventions” (D4) “The HCAs have also implemented interventions as me, increasing tremendously the dose of interventions...” (D1)	
		Detachment	↓	↓	↓	“Staff members today have not encouraged residents to drink water as usual, due to my presence, they delegated the entire role to me... so it was difficult to ensure all” (D1; D2)		
Intervention		Supportive prompts	↑	↑	↑	↑	“...Supportive prompts were most effective...” (D1; D2; D3; D4)	
		Prescriptive and Informative prompts				↑	↑	“...The prescriptive and informative prompts were of great importance in those residents who tended to distract themselves and were disoriented...” (D2; D3)
		Posture			↑	↑	↑	“...An important role was to sit near to the residents or to be at the same height as them, and touch his/her shoulder...” (D1; D2; D3; D4)

DI: diary collected in Nursing Home n. 1, *HCAs*: health care assistants, *NH*: Nursing Home

↓ preventing, hindering, or reducing fidelity; ↑ increasing or promoting fidelity

FIGURE 1. Primary intervention study and nested study: brief presentation of the main steps



NHs, Nursing Homes, *TESS-NH*, Therapeutic Environment Screening Survey for Nursing Home

SUPPLEMENTARY TABLE 1 Analysis of the study conduction according to the COnsolidated criteria for REporting Qualitative research (Tong et al., 2007)

No. Item	Guide questions/description	Strategies
Domain 1: Research team and reflexivity		
<i>Personal Characteristics</i>		
1. Inter viewer/facilitator	Which author/s conducted the interview or focus group?	Narratives were written by four researchers involved in the intervention phase; XX (see authors) supervised the researchers; XX (see authors) prepared the diaries by including questions on fidelity
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	XX was a PhD student, and experienced in conducting qualitative studies XX was a student nurse in her final year, educated at the university level; XX and XX were expert researchers
3. Occupation	What was their occupation at the time of the study?	XX was Associate Professor in Nursing Science; XX was a nursing student; XX and XX were both Full Professor in Nursing Science
4. Gender	Was the researcher male or female?	XX and XX were both female; XX and XX were male
5. Experience and training	What experience or training did the researcher have?	They were trained in conducting interviews and in collecting qualitative data ; specifically, XX was also supervised in qualitative studies in previous research projects
<i>Relationship with participants</i>		
6. Relationship established	Was a relationship established prior to study commencement?	None
7. Participant knowledge of the interviewer	What did the participants know about the researcher?	NA
8. Interviewer characteristics	What characteristics were reported about the interviewer or facilitator?	NA
Domain 2: Study design		
<i>Theoretical framework</i>		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study?	There was undertaken a qualitative descriptive study design according to Sandelowski (2000)
<i>Participant selection</i>		
10. Sampling	How were participants selected?	All researchers implementing the designed intervention in the included NHs were involved

11. Method of approach	How were participants approached?	Participants were approached face-to-face by the principal investigator (XX) and invited to participate in the study
12. Sample size	How many participants were in the study?	Four participants: these were the researchers who applied the intervention
13. Non-participation	How many people refused to participate and why?	None
<i>Setting</i>		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	The data was collected in diaries in a calm NH's room, protected by interruptions and/or sources of disturb
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	None
16. Description of sample	What are the important characteristics of the sample?	Characteristic of participants has been reported in the manuscript in terms of age, gender and background
<i>Data collection</i>		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	The questions were defined by authors and pilot tested in a NH not involved in the final study. The questions guiding the data collection have been fully reported in Table 2
18. Repeat interviews	Were repeat interviews carried out? If yes, how many?	The diary was filled in on a daily basis at the end of the intervention delivery session
19. Audio/visual recording	Did researchers use audio/visual recording to collect the data?	None
20. Field notes	Were field notes made during and/or after the focus group?	NA
21. Duration	What was the duration of the inter views or focus group?	NA
22. Data saturation	Was data saturation discussed?	NA
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	The diaries were kept by participant researchers who were free to complete and to adjust the contents in any time
Domain 3: Analysis and findings		
<i>Data analysis</i>		
24. Number of data coders	How many data coders coded the data?	Two data coders (XX and XX) and two supervisors (XX and XX) were involved
25. Coding tree description	Did authors provide a description of the coding tree?	In the data analysis section of the manuscript, the entire process is detailed Strategies aimed at ensuring rigor has been also reported in T able 3

26. Derivation of themes	Were themes identified in advance or derived from the data?	There was performed a direct content analysis by following the framework including the five domains of fidelity (Bellg et al., 2004; Carroll et al., 2007; Dusenbury et al., 2003; Resnick et al., 2005; Ibrahim & Sidani, 2016)
27. Software	What software, if applicable, was used to manage the data?	NA
28. Participant checking	Did participants provide feedback on the findings?	Findings have been presented to the participants in a meeting (November 2018) and they were asked to provide their feedback
<i>Reporting</i>		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings?	Quotations have been reported in Table 4
30. Data and findings consistent	Was there consistency between the data presented and the findings?	The consistency was ensured as reported in Table 3 and in Table 4; moreover, in the finding section, a full description of the results have been performed
31. Clarity of major themes	Were major themes clearly presented in the findings?	NA
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	NA

NH nursing homes, *NA* not applicable for the purpose of this stud