Title

Medicine Acceptability for Older People in Hospital and Care Home: The Influence of Setting

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Author Contributions

YHJ was responsible for conceptualisation, methodology and project administration of the research. FL was responsible for conceptualisation, methodology and project administration of the research whilst also providing supervision over the project. MO was responsible for project management and supervision. ND performed data analysis. FdC conducted the investigation and was responsible for formal analysis of the results. FR was responsible for the conceptualisation, data curation, methodology, project administration and supervision. TV was responsible for provision of the software as well as the conceptualisation, formal analysis of data, methodology and visualisation of data. YHJ, ND and TV were additionally responsible for drafting, reviewing and editing the manuscript. All authors read and approved the final manuscript.

Declarations

Ethics committee approval

Approvals were obtained from the Health, Science, Engineering and Technology Ethics Committees with delegated authority from University of Hertfordshire (LMS/SF/UH/03278 - 16/04/2018) and from the National Health Service (NHS) Health Research Authority (HRA) and Health and Care Research Wales (HCRW) (IRAS 246446).

Consent for publication

Not applicable.

Availability of data and materials

The datasets during and/or analysed during the current study available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests

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Abstract

Background: Medicines acceptability is likely to have significant impact on older people's adherence and consequently, treatment effectiveness.

Objective: To explore the influence of setting on medicines acceptability in older people.

Design: Multicentre, prospective, cross-sectional, observational study.

Setting: One care home and one elderly care hospital ward in London, UK.

Subjects: Individuals on ≥ 1 medicine(s) and aged ≥ 65 years.

Methods: Data driven approach using multiple observer-reported outcomes analysis tool to distinguish between positively and negatively accepted medicines.

Results: 263 observer reports from the care home (n=97) and hospital ward (n=166) involving 155 distinct medicinal products were assessed. Collectively, medicines appeared better accepted by patients at the hospital. Differences appeared to be driven by variations in solid oral dosage form acceptability. Patients with dysphagia poorly accepted medicines in both settings, as expected. Solid oral dosage forms were unexpectedly better accepted in the hospital than in the care home in patients without dysphagia.

Conclusions: Medicines acceptability was affected by patient's characteristics, dosage form type and setting. Changes in care practices between care home and hospital may affect medicine administration and lead to variations in ability and willingness of patients and carers to use the product as intended.

Keywords

Medicine; acceptability; older population; swallowing disorders; solid oral dosage form

Introduction

Older people of the same age can appear different due to variances in physiological and cognitive health [1]. As such, longevity does not necessarily correlate to good health and quality of life [2]. Polypharmacy, characterised as taking more than five medicines, has high prevalence amongst older populations [3] and is recognised as a potential for harm [4]. The number of medicines may influence patient preference towards particular dosage forms and medication adherence [5]. Acceptability, defined as 'the ability and willingness of a patient to self-administer, and also of any of their lay or professional caregivers, to administer a medicinal product as intended' [1] is a fundamental aspect of adherence. An acceptable medicine should in theory improve adherence to prescribed treatment [6], although adherence remains a complex factor of medication usage [7].

Medicines acceptability requires an understanding of patient characteristics, drug therapy-associated factors and socio-cultural factors [8]. Independent older patients who reside at their own residence often manage their own medicines, although some may be assisted by informal (i.e. family and friends) or formal (i.e. trained) carers. By contrast, older people in residential or care homes may receive assistance from formal carers for day-to-day activities including medicines administration, often packaged in compliance aids [9,10]. In hospitals, registered nurses, with exceptional cases when patient self-administration schemes are in place, usually manage medicines.

Many factors affect the administration of medicines to older patients in a particular care setting. Changes in setting have been shown to influence observed medication errors in older patients and the errors appeared to be compounded in the presence of co-morbidities and polypharmacy [11]. Nurses' or carers' ability and willingness to administer medicines to older patients as intended could also determine the patient acceptability of medicines and resultant treatment outcomes [12,13].

It is important to understand how the interplay of multiple factors could affect an older person's perception of their medicines leading to incidences of non-adherence, medication errors and unintended harm in different settings. Our aim was to explore factors affecting acceptability in older patient populations in two care settings, a care home and a care of elderly hospital ward.

Methods

We used a data-driven approach based on real-life observer-reported outcomes (ObsRO): CAST - ClinSearch Acceptability Score Test ®. Initially developed for the paediatric population [14,15], the tool has been transposed for the older population [16], to discriminate between positively and negatively accepted formulations in vulnerable populations [17-23]. ObsRO allows standardised data collection in these populations, who may be unable to provide reliable and valid self-evaluations due to their development status, or the deterioration of physical and cognitive abilities. The validity and the reliability of the tool have been previously established [16,24]. We followed published methodology, briefly described hereafter, and shown in Video S1.

Study design and setting

Prospective, cross-sectional, observational study conducted between June 2018 and February 2019, at a north-west London care home and the elderly care ward at an acute tertiary academic hospital in London.

Participants

Participants who were aged 65 years or over; receiving at least one medicine; and had the capacity to consent were included. Individuals were excluded if they were unable to or did not consent. All eligible individuals were approached by a member of the research team without any randomisation. Written consent was obtained before data collection.

Medication Acceptability Questionnaire

After consent was given, a member of the research team joined nurses to observe the administration of the first medicine due to be administered at the next medication round for each participant and completed a standardised questionnaire in real time.

The following events, behaviours and methods used to aid administration were recorded [22]:

- results of intake (the required dose fully, partly or not taken at all);
- patient reaction during administration using a 3-point hedonic face scale (positive, neutral or negative reaction);
- preparation time (from opening any packaging to having a required dose of medication ready to use, including all handling and modifications), and administer dose (from a required dose of medication ready to use to the end of the intake). The

sum of the times of preparation and administration, recorded at 10 second intervals, were classified as short (≤ 20 seconds), medium (30 to 60 seconds), or long (> 60 seconds);

- dividing the intake of a dose which cannot be taken whole;
- altering intended use (modify dosage form such as tablet crushed or capsule opened; use another route/mode of administration);
- using food/drink to mask taste or ease swallowing;
- using a device not provided (e.g. oral administration syringe from another medication);
- any patient resistance, such as the patient had to force themselves or opposed taking the medication. Note: "restraint" rather than "resistance" was used in the original acceptability reference framework; the change of term does not alter the meaning and interpretation of results.

The researcher also entered the exact name of the medicine under investigation, information on the context (e.g. the place of medicine administration), and characteristics of the patient (e.g. age, sex, swallowing disorders) and the treatment (e.g. the required dose) as recorded in the patient's medical record [22]. Further information on the medicine (e.g. formulation) was extracted from the summary of product characteristics.

Statistical Methods

Acceptability was scored using the acceptability reference framework, which provides comprehensive acceptability scores. This tool is based on multivariate analysis of a large set of 2004 evaluations composed of those from England - explored in this paper - and additional evaluations collected in French hospitals and care homes since 2016 using the standardised questionnaire.

First, a factorial method (Multiple Correspondence Analysis) visualised key relationships between all the evaluations into a low-dimensional space: the three-dimensional acceptability map. The evaluations were positioned onto the map according to their similarities, between ideal and worst combinations of observed measures. Subsequently, the evaluations were partitioned into two meaningful clusters using hierarchical clustering on principal components and k-means consolidation. The two clusters characterised by the observed measures significantly overrepresented in each of them, defined two coherent acceptability

profiles: "positively accepted" and "negatively accepted", represented by green and red areas on the map, respectively.

As acceptability evaluation must necessarily be relative, the acceptability scores of different subgroups of interest were compared within the reference framework as follows: a subgroup of interest was positioned on the map at the barycentre of its evaluations; if the barycentre, along with the entire 90% confidence ellipsis surrounding it, was positioned in the green area of the map, the subgroup of interest was considered as accepted. A minimum of 30 evaluations were required to obtain a reliable acceptability score with a satisfactory precision. Distinct acceptability scores were significantly different if confidence ellipses did not overlap on the map. The evaluations collected in this study were partitioned into two subgroups according to location: hospital or care home. Both subgroups of interest were positioned on the map at the barycentre of their evaluations to obtain a reliable acceptability score [16,25]. Each subgroup (hospital and care home) was then successively partitioned according to the medicine's dosage forms and the patient's ability to swallow. In each case acceptability was scored to explore the influence of setting.

Statistical tests were used to assess the significance of the differences observed between the different subgroups in terms of measures composing the acceptability scores, medicine features and patient characteristics. When there was a minimum expectation of 5 for 80% of cells without any null expectation Pearson's Chi-squared test (χ^2) was used, alternatively Fisher's exact test (F) was used.

Data analyses were performed using R version 1.0.136© (RStudio Team (2016). RStudio: Integrated Development for R. RStudio, Inc., Boston, MA, USA). The R packages FactoMineR [26] and MissMDA [27] were used to perform multivariate analysis and to handle missing data.

Results

Patients and Medicines

263 evaluations were collected: 97 from the care home and 166 from the hospital elderly care ward.

The average age of the participants was 83 years (range 65-99 years) and 55% were women. Twenty percent of evaluations involved patients with swallowing disorders diagnosed a priori and recorded in the patient's medical record. There were no significant differences in terms

of patient sex (χ^2: p = 1), age groups (χ^2: p = 0.05), swallowing disorders (χ^2: p = 0.72), muscular or rheumatologic disorders of the upper limbs (χ^2: p = 0.09) and previous exposure to treatment (χ^2: p = 1) between the two settings. Disorders of memory were recorded for 60% of evaluations at care home and 24% at hospital (χ^2: p < 0.001). Caregivers' involvement in administration was reported more at the care home (73%) than at hospital (59%) [χ^2: p = 0.032]. Care home data were collected in the morning, the evening and at bedtime, while they were mainly performed at noon, mid-afternoon and in the evening at the hospital.

One hundred and fifty-five distinct medicinal products were assessed and comprised solid oral dosage forms (SODF) (77% of evaluations), oral liquid preparations (14%), and other dosage forms e.g. injections, buccal preparation, ocular preparation, inhalants, topical and nasal preparations (9%). Evaluations mainly involved medicines from the central nervous system pharmacological group (38%), the alimentary tract and metabolism group (22%) and the cardiovascular system group (12%). There were no differences between the two settings in terms of categories of dosage forms (χ^2: p = 0.22) and the main anatomical/pharmacological groups of the Anatomical Therapeutic Chemical (ATC) classification system (χ^2: p = 0.06).

Polypharmacy was noted in the care home setting with 41% of patients taking between 5 and 9 medicines and 58% being treated with 10 medicines or more. In the hospital, a similar percentage of patients were prescribed between 5 and 9 medicines (38%), but only 25% were on 10 medicines or more.

Medicine Acceptability in Different Settings

Overall, medicines appeared to be better accepted at the hospital: the barycentre of the 166 evaluations from the hospital, and entire confidence ellipses surrounding it, were located in the "positively accepted" profile. The barycentre of the 97 evaluations from the care home was similarly located into the green area, but 47% of the confidence ellipses fell within the "negatively accepted" profile.

The most common form of medicines in this study, SODF, could be classified as positively accepted at the hospital, but not in the care home as illustrated by a significant part of the confidence ellipsis (31%) in the red area of the map (Figure 1). The patient's ability to swallow is a common age-related alteration likely to affect ability and willingness to use SODFs as intended. As expected, SODFs were classified as accepted in older patients

without swallowing alteration regardless of the setting, while the barycentre of the 35 evaluations collected in patients with swallowing disorders, along with the entire confidence ellipses surrounding it, was located in the red, negative area of the acceptability map. The evaluations of SODF intake were similarly partitioned into two subgroups according to the patient's ability to swallow for each setting (Figure 2). Although there were insufficient evaluations ($n < 30$) to determine statistical significance, SODF tended to be non-accepted for older people with swallowing disorders regardless of setting. In contrast, for older people without swallowing disorders, SODF were fully located in the green, acceptable area of the map for hospital inpatients, whilst this was not the case in the care home. Table 1 presents the characteristics of the patients and the medicines for in both settings for patients without swallowing difficulties who had taken SODF.

Figure 1. *Acceptability profiles of solid oral dosage form (SODF) in the older patients depending on settings: Hospital and Care Home.*

Figure 2. *Acceptability profiles of solid oral dosage form (SODF) in the older patients with (SD+) and without (SD-) swallowing disorders depending on settings: Hospital and Care Home.*

Table 1. *Characteristics of the patients and the products for evaluations of solid oral dosage form (SODF) taken by patients without swallowing disorders (SD-) at Hospital and Care Home*

Negative observations were reported more often in patients without swallowing disorders at the care home, including a negative reaction, the use of food/drink, or dividing the intake of the required dose which cannot be taken as a whole (Table 2). The preparation and administration time profiles also differed, with higher proportion of observations involving either very short (≤ 20 seconds) or long (> 60 seconds) time in hospital than in the care home. Using a straw to ease administration in patients encountering difficulties to hold a drink or a cup was observed in both settings but used more in the care home. Tablets were crushed to allow mixing with drink or food mainly and using a device such as a spoon or a straw to achieve administration for 10% of evaluations in the care home, but only once in the hospital. Modifications prior to administration were recorded for 51% of the evaluations in patients with swallowing disorders taking SODF, with no difference between settings (χ^2: $p = 0.82$); and no difference observed between modification of tablets or capsules irrespective of swallowing difficulties (χ^2: $p = 0.48$).

Oral liquid preparations, the second form of medicines in this study, seemed to be negatively accepted in both settings. However, considering the low number of evaluations for each setting ($n < 30$), we could not discuss such acceptability tendency.

***Table 2**. Observational measures per variables for evaluations of solid oral dosage form (SODF) taken by patients without swallowing disorders (SD-) at Hospital and Care Home*

Discussion

Using an established data-driven approach based on real-life observer-reported outcomes, we have shown an association between care settings and the acceptability of medicines, with more negative acceptance in a care home than in a hospital. This difference was mainly caused by acceptability differences for SODFs, such as tablets and capsules, in participants without swallowing disorders.

Medicines administration in hospital and care home settings have been reported previously [34,41]; however, different methodologies were used making comparison difficult. To our knowledge, this is the first study to use a standardised tool to evaluate and compare medicine acceptability in patients in both settings.

Our study has some limitations. Participants were recruited on a voluntary basis and the majority were on oral medicines. The acceptability of other dosage forms, such as topical use patches or inhalers, which may be viable alternatives in case of swallowing difficulties, was not investigated. Individuals who were unable to consent were not included. These patients may have had severe cognitive issues or may be inherently predisposed to dysphagia due to co-morbidities and polypharmacy and therefore issues with medicines acceptability [39,40], thus limiting the generalisability of the findings. To avoid bias caused by prior administration of other medicines, only the first medicine dose was included in the observed data, regardless of the size of the solid oral dosage form. The acceptability of subsequent medicines taken at the same time may have been affected, but this was not captured. Whilst the number of medicines prescribed to the patient was recorded from the patient's medical records, this was not the same as the number of medicines that had to be taken for the observed round. For this reason, the full extent of the effect of polypharmacy on medicines acceptability was not explored in this study.

SODFs were more negatively accepted in the care home than in the hospital in participants without swallowing difficulties. This was attributed to proportionally higher use of divided doses, food/drink, extra device and alteration of medicines in the care home than in the hospital, which may be due to the nature of institutional care. In a care home, the long stay nature of the resident and associated familiarity with the care staff could contribute to the

consideration of patient views in medicine administration. Furthermore, medicines are prepared by a nurse or trained carer in accordance with individual patient preference sheets, which outline independent or supervised medicines consumption; how SODFs are taken (i.e. one-by-one or all at the same time); original or modified dosage form administration (e.g. crushed into powder, capsules opened etc.) and taken with or without food or drink.

In hospitals, multidisciplinary teams including clinicians, pharmacists, speech and language therapists and nurses are involved in medication decision making and care of patients, which might facilitate better prescription and administration of medicines. Similarly, educational sessions for nursing staff and guidelines and local policies might be more available in hospitals than in care homes, which could limit the risks of inappropriate administration of medicines [28,29]. This heterogeneity between hospital and care home settings should be recognised and where possible, addressed to reduce the variability in the care delivered to all older patients who may transition between health and care environments.

SODFs tended to be negatively accepted in patients with swallowing difficulties regardless of the setting, with alterations reported as common practices in both hospitals and care homes to aid swallowing [24]. The practice implications of alterations are considerable, especially in the care home setting, where further manipulations including the use of food or drink were used to improve the acceptability and achieve administration of the full dose. The alteration of a medicine's form renders unlicensed use. Whilst the unlicensed practices could be required to achieve administration in specific circumstances (e.g. only available as SODF for patients with severe dysphagia), they may lead to medication errors, bioavailability issues and changes in treatment safety and efficacy [30,31]. Changes could be aggravated by factors such as frailty, comorbidity and polypharmacy. Unnecessary manipulations have been reported in care homes [32-34] aggravating the already significant risk of medication errors in this vulnerable population [35].

Liquid medicines are often considered a reasonable and logical alternative to SODFs for patients with swallowing disorders. Interestingly, these medicines seemed more likely to be negatively accepted in both settings. Such findings, which must be confirmed, are in line with previous results highlighting the crucial role of swallowability and palatability of oral liquid pharmaceutical products in older people receiving institutional care [18]. One issue related to the poor acceptance of liquid medicines could be bad taste [31], as it is more difficult to mask the bitter taste of active ingredients in liquids than in SODFs. Secondly, the textural and

rheological properties of liquids needs consideration as they affect the swallowing safety in patients with dysphagia [37].

Poor acceptability to medicines may contribute to medication administration error. Variances in medication administration errors have previously been reported in care home and hospital settings. Santos et. al reported an error rate of 30.8% for those without dysphagia and 57.3% for those with dysphagia in an undisguised observational study across six North England care homes [33]. Kelly et. al prospectively assessed oral and enteral administration errors in older patients with and without dysphagia and reported errors in 817 of 2129 (38.4%) medicines administrations [38], of which, 313 were in dysphagic patients. Our findings in the differences in medicine acceptability in different settings and patient groups can help to explain these variances in medication administration errors.

This exploratory study paves the way for future studies in other sites as work practices may differ from care home to care home and from hospital to hospital. Furthermore, implementing the model with new data will allow us to strengthen our analysis, and to investigate other objective (such as time of medication intake, duration of the prescription) or subjective factors (aspect of personality psychology, patients' perspective of drug intake) in order to improve our knowledge on medicine acceptability in the older population.

Our findings highlight the need for focussed research on medicines acceptability in old age taking into account context and setting. Collaboration between healthcare professionals, researchers and pharmaceutical industry, with patients as active partners, during the design and evaluation can help to understand the multi-faceted concept of medicine acceptability in older populations, to ultimately minimise medicine non-adherence, errors and harm.

Conclusions

Medicine acceptability is an important factor affecting adherence and therapeutic outcomes of older people. Overall, medicine acceptability by patients was more negative in the care home setting than the hospital. For patients with swallowing difficulties, medicines were more likely to have negative acceptability in both settings. For patients without dysphagia, solid oral dosage forms were surprisingly better accepted in the hospital environment than the care home. This was attributable to greater consideration of patient preference in the care home, with the use of divided doses, food and/or drink, extra device and alteration of medicines to aid administration. Understanding the complex factors contributing to the

acceptability of medicines in older populations could help optimise medication use and safety.

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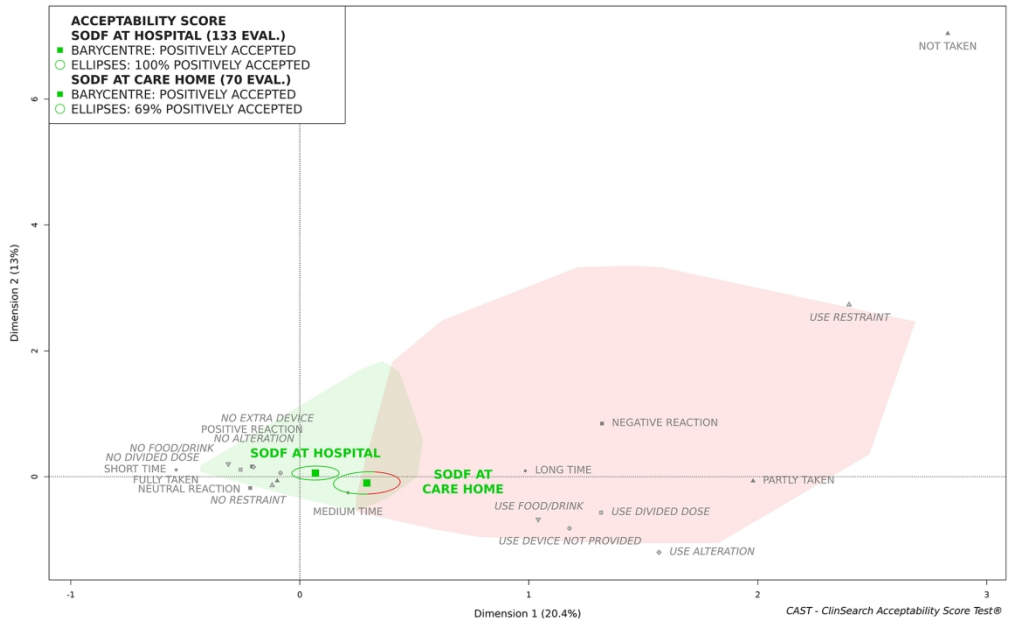

Figure 1. Acceptability profiles of solid oral dosage form (SODF) in the older patients depending on settings: Hospital and Care Home.

97x60mm (500 x 500 DPI)

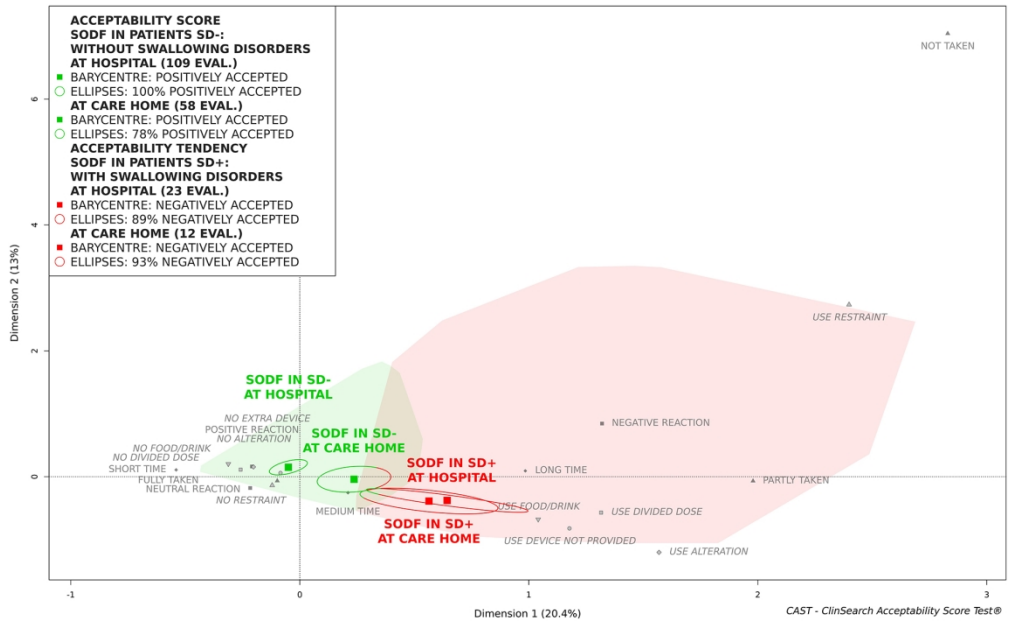

Figure 2. Acceptability profiles of solid oral dosage form (SODF) in the older patients with (SD+) and without (SD-) swallowing disorders depending on settings: Hospital and Care Home.

97x60mm (500 x 500 DPI)

Table 1. *Characteristics of the patients and the products for evaluations of solid oral dosage form (SODF) taken by patients without swallowing disorders (SD-) at Hospital and Care Home*

	Hospital (n=109)	**Care Home (n=58)**	**Statistical Test**
Sex			
Women	56 (53) [a]	32 (55)	χ^2 [b]: p = 0.9 (ns) [c]
Men	50 (47)	26 (45)	
	md [d]: 3		
Age group			
[65-75]	20 (18)	0 (0)	
[75-85]	48 (44)	22 (38)	χ^2: p < 0.001 (*)
[85-95]	40 (37)	35 (60)	
[95-99]	1 (1)	1 (2)	
Memory disorders			
Memory disorders	24 (23)	39 (68)	χ^2: p < 0.001 (*)
No memory disorders	82 (77)	18 (32)	
	md: 3	*md: 1*	
Muscular or rheumatologic disorders of the upper limbs			
Muscular disorders	32 (29)	17 (30)	χ^2: p = 1 (ns)
No muscular disorders	77 (71)	40 (70)	
		md: 1	
Treatment exposure			
Already taken	107 (99)	57 (98)	F [e]: p = 1 (ns)
First intake	1 (1)	1 (2)	
	md: 1		
Person in charge of administration			
Caregiver involvement	59 (55)	38 (67)	χ^2: p = 0.18 (ns)
Self-administration	49 (45)	19 (33)	
	md: 1	*md: 1*	
Main anatomical / pharmacological groups [f]			
Nervous system	49 (45)	24 (41)	
Cardiovascular system	15 (14)	12 (21)	
Alimentary tract and metabolism	16 (15)	11 (19)	χ^2: p = 0.46 (ns)
Blood and blood forming organs	12 (11)	5 (9)	
Anti-infectives for systemic use	9 (8)	1 (2)	
Other groups (<5%)	8 (7)	5 (9)	
Type of SODF			
Tablet	91 (83)	47 (81)	χ^2: p = 0.85 (ns)
Capsule	18 (17)	11 (19)	

[a] n(%): number and percentages; [b] χ^2: Pearson's Chi-squared Test P-value; [c] *: statistically significant; [d] md: missing data; [e] F: Fisher's Exact Test P-value ; [f]: 1st levels of the ATC classification system

***Table 2**. Observational measures per variables for evaluations of solid oral dosage form (SODF) taken by patients without swallowing disorders (SD-) at Hospital and Care Home.*

	Hospital (n = 109)	**Care Home (n = 58)**	**Statistical Test**
Result intake			
Fully taken	103 (94) [a]	56 (97)	
Partly taken	2 (2)	0 (0)	F [b]: p = 0.85 (ns) [c]
Not taken	4 (4)	2 (3)	
Patient reaction			
Positive	27 (25)	1 (2)	
Neutral	70 (65)	44 (76)	χ^2 [d]: p < 0.001 (*) [e]
Negative	10 (9)	13 (22)	
	md [f]: 2		
Preparation and administration time			
Short	31 (28)	8 (14)	
Medium	22 (20)	40 (69)	χ^2: p < 0.001 (*)
Long	56 (51)	10 (17)	
Divided dose			
Used divided dose	9 (8)	14 (24)	χ^2: p = 0.009 (*)
Alteration			
Used alteration	1 (1)	6 (10)	χ^2: p = 0.013 (*)
Food/drink			
Used food/drink	5 (5)	15 (26)	χ^2: p < 0.001 (*)
Extra device			
Used device not provided	10 (9)	22 (38)	χ^2: p < 0.001 (*)
Restraint			
Used restraint	3 (3)	5 (9)	χ^2: p = 0.19 (ns)

[a] n(%): number and percentages; [b] F: Fisher's Exact Test P-value; [c] ns: not statistically significant; [d] χ^2: Pearson's Chi-squared Test P-value; [e] *: statistically significant; [f] md: missing data