#### **ORIGINAL ARTICLE**



# Solid Oral Dosage Forms Use in Adults with Neurological Disorders and Swallowing Difficulties: A Scoping Review

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## Abstract

Swallowing difficulties affects the deglutition of solid oral dosage forms (SODFs) and it is a common problem among neurological disorders. Interventions may improve the use of SODFs in healthcare settings. The aim of this study was to map the available research about the interventions aiming the effective and safe use of SODFs in adults with neurological disorders and swallowing difficulties and to identify potential literature gaps in this scientific field. A scoping review was carried out based on Joanna Briggs Institute guidelines and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews, in PubMed, Scopus, and SciELO databases (March 2021). Peer-reviewed observational studies assessed the effectiveness and safety of SODFs in adults with neurological disorders and swallowing difficulties in the healthcare organizations setting were included. 11 studies were included (three case reports, two mixed-methods intervention studies, and six analytic studies). The frequency of women ranged from 49 to 67%, and the age from 57 to 91 years. Most studies (n=7) included elderly patients, Parkinson (n=6) and dementia (n=3). Medication review was the most frequently reported intervention, 35% (9/26). In most studies, interventions were targeted to patients during hospitalization (n=7) and performed by physicians (n=8). At least 20 different outcomes were evaluated in the studies. Implementing specific protocols for using SODFs aimed at the swallowing difficulties of this population is not a common practice. Additional studies on interventions aimed at optimizing SODFs are needed to support the safety and efficacy of oral therapy in this patient group.

Keywords Deglutition disorders · Deglutition · Dosage forms · Pharmaceutical preparations · Drug utilization

## Introduction

Swallowing difficulty, or dysphagia is a perceived condition or real disturbance in forming or moving bolus safely from the oral cavity to the esophagus [1], which also affects the deglutition of solid oral dosage forms (SODFs) [2]. This is a common problem among older people [3] and among

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neurological disorders, such as stroke, Parkinson's disease (PD), Alzheimer's disease, and dementia [4, 5]. Moreover, in hospitals and aged care facilities, 50-68% of older people may experience swallowing difficulties [6, 7]. For this reason, interventions aimed at improving the use of SODFs in health organizations proved beneficial [8, 9], mainly because the multidisciplinary team demonstrates a lack of knowledge on the subject [10–13].

Interventions for SODFs use optimization for patients with swallowing difficulties aim to enable the best possible outcomes. For instance, one of the primary interventions for safe and effective SODFs use is the medication review, mainly if performed with a pharmacist [14]. Medication review aims to reduce the number of prescribed medications [15] and assess the possibility of other administration routes or pharmaceutical alternatives [16, 17]. The different physical characteristics of SODFs (i.e., shape, size, texture, and taste) are directly associated with reducing the ability to swallow [18–20] and medication review may be helpful.

Several studies reported interventions strategies to facilitate administration, such as some postural/compensatory techniques to make SODFs easier to swallow [21–23] or to mix SODFs with foods or liquids [16, 24, 25]. These can be essential interventions to help decisions regarding medications and draw self-management plans. Nevertheless, when performing these interventions is impossible, modification may be considered. The modification is any alteration of an oral dosage form (liquid or solid) [26] that may be carried out by healthcare staff, carers, or even by patients [27]. However, several factors associated with inadequate modification of SODFs may cause severe risks to the patient, impairing medications' effectiveness and safety.

Effectiveness can be impaired, for example, when modifying enteric-coated tablets (gastro-resistant), as the drug's protection (against light, moisture, and degradation by gastric acid) is missed [28]. In addition, an insufficient yield can be obtained after SODFs modification, especially with crushing tablets [29], which may be even more relevant for narrow therapeutic index drugs [30]. Also, the unacceptable taste or smell resulting from modifying some SODFs, such as capsules and film-or sugar-coated tablets, are limiting factors, as the patients may refuse to take their medication [31]. The drug's safety may be severe, and it may even be the reason why modification of some SODFs is contraindicated. For instance, removing coatings of SODFs of irritating mucosal drugs results in early drug release and gastric adverse reactions [28]. Additionally, modifying sustainedrelease SODFs can be even more harmful to the patient because higher drug dose will be available, and the risk of adverse reactions, or even death, will increase [32, 33], especially for narrow therapeutic index drugs [34].

Some systematic reviews have investigated the patient adherence (Shariff et al., [5]), and interventions to improve the use [26, 35] of SODFs in older adults with swallowing difficulties in a variety of settings. However, information about the management of swallowing difficulties in adults with neurological disorders is currently limited to specific diseases [4, 36] and none of these reviews have focused on use of SODFs for this population. Thus, we aimed to provide the current state of knowledge on this topic using a scoping review. The purpose of this scoping review was to map the available published research about the interventions aiming at the effective and safe use of SODFs in adults with neurological disorders and swallowing difficulties and to identify potential literature gaps in this scientific field. The objectives of this scoping review were to:

- 1. Characterize the study populations.
- 2. Identify the categories, outcome measures, and the main characteristics of the interventions (i.e., targets and deliverers; mode of delivery; duration; costs/resource requirements).

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3. Provide the studies health institutions settings.

## Methods

## **Protocol and Registration**

The scoping review protocol is registered in the Open Science Framework (osf.io/u8sdv/), available under the registration number https://doi.org/10.17605/OSF.IO/U8SDV.

#### **Study Design**

A systematic scoping review was conducted according to the Joanna Briggs Institute Methodology for Scoping Reviews [37, 38] and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR) Checklist and Explanation [39].

The research questions guiding this study were as follows:

- 1. What is the profile of adults with neurological disorders and difficulties in swallowing non-modified SODFs?
- 2. What are the categories of interventions aiming at optimizing the effective and safe use of SODFs in adults with neurological disorders and swallowing difficulties?
- 3. What are the main characteristics of the interventions aiming at optimizing the effective and safe use of SODFs in adults with neurological disorders and swallowing difficulties?
- 4. What are the outcome measures reported in studies on interventions aiming at optimizing the use of SODFs in adults with neurological disorders and swallowing difficulties?

## **Eligibility Criteria**

We included peer-reviewed research articles, available in full-text, designed as observational studies that assessed the effectiveness and safety of SODFs in adults with neurological disorders and swallowing difficulties in the healthcare organizations setting. No restrictions regarding studies' publication date were applied.

The elements of the inclusion criteria according to the proposed by The Joanna Briggs Institute [37] were as follows:

Population (types of participants): this review considered studies involving adults (≥ 18 years) with neurological disorders (any type) with difficulties in swallowing SODFs, regardless of sex. According to the World Health Organization, neurological disorders are diseases of the central and peripheral nervous system, includ-

ing: epilepsy, Alzheimer disease and other dementias, cerebrovascular diseases including stroke, migraine and other headache disorders, multiple sclerosis, PD, neuroinfectious, brain tumors, traumatic disorders of the nervous system due to head trauma, and neurological disorders related to malnutrition [40].

- 2. Concept (types of interventions): studies evaluating interventions in the management of solid oral pharmacotherapy were included. Eligible studies were not restricted to any specific type of therapeutic drug class not limited by the number of medicines prescribed. Eligible interventions should specifically target the effective and safe use of SODFs, according to the Medicine Optimization Recommendations. For the aim of this review, we considered interventions that target any of the following: 'systems for identifying, reporting and learning from medicines-related patient safety incidents'; 'medicines-related communication systems when patients move from one care setting to another'; 'medicines reconciliation'; 'medication review'; 'selfmanagement plans'; 'patient decision aids used in consultations involving medicines'; 'clinical decision support'; 'medicines-related models of organizational and cross-sector working' [41]. Interventions targeting patients, healthcare organizations, or healthcare professionals were included.
- Context: studies conducted in health institution settings (public or private), regardless of care level, location or country were included. Articles published in non-Roman characters were excluded.

## Information Sources and Search Strategy

An electronic search was performed in PubMed, Scopus, and SciELO (updated on 18 March 2021) without time or language limits (full search strategies in Online Resource 1). Manual searches were conducted in the reference lists of included studies and Google/Google Scholar. Relevant non-indexed registers, as well as websites of journals that displayed a strong interest in swallowing disorders, information systems, and science events annals were also screened for additional papers.

#### Selection of Sources of Evidence

After registers retrieval and duplicates removal (EndNote version X9.3.1, Clarivate Analytics, PA, USA), two reviewers independently screened titles and abstracts to identify irrelevant records. Potentially relevant papers were retrieved in full, and their citation details were imported into Microsoft Office Excel (Microsoft, USA). In a second stage, full-text articles were independently evaluated by the two researchers to identify those eligible for this review.

Discrepancies among reviewers during these steps were conciliated in a consensus meeting using a third researcher as a referee.

#### **Data Charting Process and Items**

Data were extracted and analyzed by two independent reviewers and discussed with a third researcher when necessary using a data extraction form developed for this study following per under relevant methodological guidance [38], in Microsoft Office Excel (Microsoft, USA) (Online Resource 2). The following variables were collected:

- 1. Study: authors, year of publication, country of origin, design, setting, aims, duration.
- 2. Population: sample size, patient demographics (age, sex, type of neurological disorder, and other important condition), type of SODFs.
- Intervention details: (i) category classified according to the Effective Practice and Organization of Care (EPOC) taxonomy, i.e., 'Delivery arrangements', 'Financial arrangements', 'Governance arrangements', 'Implementation strategies' [42]: targets and deliverers; mode of delivery; duration; costs/ resource requirements; (ii) medicine optimization recommendations [41].
- 4. Outcome measures used to evaluate the interventions.
- 5. Key findings: summary of key results.

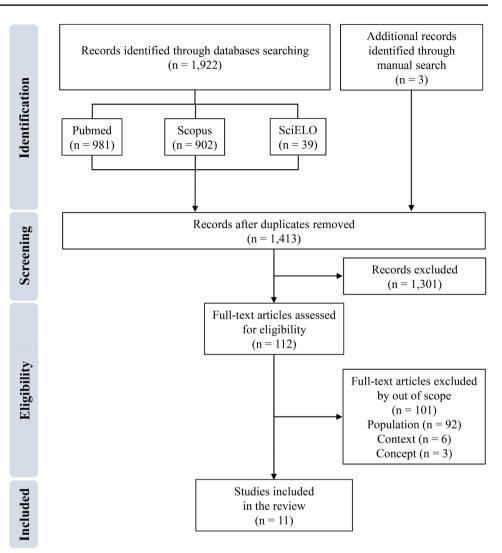
## **Synthesis of Results**

The main findings (data from studies, participants, interventions, and healthcare settings) were summarized and were reported using descriptive statistics such as absolute frequencies and means. A narrative summary accompanied the tabulated and charted results, considering the outcome measures, instruments, and subgroup populations and their definitions.

## Results

A total of 1922 records were identified through electronic database and three additional articles were added by manual search. Following the removal of duplicates, 1413 records were screened, of which 1301 articles were excluded. The remaining 112 articles were read in full of which 101 were excluded (population: 92, context: 6, concept: 3—Online Resource 3). Finally, 11 studies were included for analysis (Fig. 1).

Fig. 1 Workflow diagram of publication selection process using PRISMA-ScR Guidelines



## **Overall Characteristics of Included Studies**

The included studies were published between 1994 and 2020, being mostly conducted in Germany (n = 3) and USA (n = 3) and with follow-ups ranging from 3 days to 10 months. Three case reports [43–45], two mixed-methods intervention studies [46, 47], and six analytic studies were included (two cohorts [48, 49] and four cross-sectionals [50–53]) (Table 1).

## Population

The sample size ranged from 1 (i.e., case reports) [43-45] to 1873 patients [52], while the number of healthcare professionals ranged from 30 [51] to 32 [46]. Excluding the case reports, the frequency of women in the studies varied between 49% [49] and 67% [53], and the age of the participating patients ranged from 57 [44] to 91 years [45]. Most studies (n=7; 63.6%) assessed elderly patients

(age  $\geq$  60 years) [43, 45, 47–50, 53]. Among the neurological disorders, PD was the most reported (n = 6; 54.5%) [43, 44, 47–50], whereas in other three studies (27.3%) patients with dementia were evaluated [47, 51, 52]. All studies evaluated tablets; six provided their data through hard gelatin capsules [44, 46, 47, 50, 51, 53], and four involved dispersible or disintegrating dosage forms [46–49] (Table 2).

#### Intervention's Categories

Intervention categories were classified according to the Medicine Optimization Recommendations [41]. Of the total 11 studies, some conducted more than one intervention category, totalling n = 26. Around one third of the interventions (n = 9/26; 35%) were medication review; medicines-related models of organizational and cross-sector working represented 15% of interventions (n = 4/26) (Table 3).

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Authors, year (country)	Study design	Study settings	Study aims	Study duration
[46] (UK)	Mixed	Public health institution, hospital: subacute stroke rehabilitation unit	To describe how, through a multiprofessional, collaborative approach, safe administration of oral medicines to patients with dysphagia can be achieved within the context of stroke care	6 months
[50] (Germany)	Cross-sectional	Cross-sectional Public health institution, university medical center	To evaluate the prevalence, characteristics, and predictors of the difficulty of swallowing SODFs in PD	45 days
[43] (USA)	Case report	Public health institution, hospital: emergency department and internal medicine unit	To report the case of an old woman with PD, Alzheimer's dis- ease, and hypertension with unusual adverse reactions to oral bisphosphonate tablets	3 days
[51] (Australia)	Cross-sectional	Cross-sectional Public and private health institutions, nursing home	To investigate the time taken to administer medications to residents, including those with complex care needs such as cognitive impairment and dysphagia	12 days
[48] (Germany)	Cohort	Clinic	To evaluate the improvement of the effects of PD with levo- dopa + benserazide dispersible formulation in patients with swallowing disorders, when compared to conventional tablet formulation	Not reported
[44] (Canada)	Case report	Public health institution, hospital: psychiatry unit and neurological unit	To report a case of an old man hospitalized for relapse of psy- chotic symptoms with a previous diagnosis of schizophrenia and PD and dysphagia	Not reported
[47] (Spain)	Mixed	Public health institution, hospital: internal medicine unit	To improve the administration of oral medicines in patients with dysphagia by changing the pharmaceutical formulation pre- scribed to tolerable textures	4 months
[52] (Norway)	Cross-sectional	Cross-sectional Public health institution, nursing home	To examine the practice of concealing medicines in patients' foodstuff	Not reported
(49) (USA)	Cohort	Public and private health institutions, clinic	To compare preferences for ODT with those of the conventional tablet of the anti-parkinsonism combination levodopa + carbi-dopa in subjects with PD	Not reported
[45] (USA)	Case report	Public health institution, hospital	To report the case of an old man with a 3-year history of Alz- heimer's dementia, who used intravenous sodium valproate for agitation and dysphagia	Not reported
[53] (Germany)	Cross-sectional	Cross-sectional Public health institution, hospital	To investigate the prevalence of difficulties swallowing SODFs in patients with stroke-induced dysphagia; evaluate whether the swallowing of particular SODFs increases the risk of penetra- tion and aspiration, and whether safe and effective swallow- ing depends on the type of SODFs; assess whether routinely performed assessment tests reliably identify patients who experience difficulties swallowing SODFs, and how often inap- propriate SODFs modifications occurred	10 months

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Authors, year	Sample size (% of women)	Age, years (Mean $\pm$ SD)	Types of neurological disorder	Other important condi- tions	Types of solid oral dos- age forms
[46]	22 nurses, 10 health- care assistants (not reported)	Not reported	Stroke	No	Tablets, hard gelatin capsules, ODT
[50]	150 (118 patients*, 32 controls**) (36.7% (33% patients*, 50% controls**))	Not reported ( $69.0 \pm 10.1$ patients*, $68.1 \pm 10.7$ con- trols**)	PD	No	Tablets, hard gelatin capsules
[43]	1 patient (100%)	86	PD, Alzheimer's disease	Arterial hypertension, elderly	Tablets
[51]	30 nurses (not reported)	Not reported	Dementia	Elderly	Tablets, hard gelatin capsules
[48]	19 patients (53%)	66.05 (±8.32)	PD	Elderly	Tablets, dispersible dosage forms
[44]	1 patient (0%)	57	PD	Schizophrenia	Tablets, hard gelatin capsules, soft gelatin capsules
[47]	23 patients (65%)	85 (±7.4)	Dementia, cerebrovas- cular disease, PD	Elderly	Tablets, hard gelatin capsules, enteric- coated (gastro- resistant) tablets, oral powders
[52]	1873 patients (not reported)	Not reported	Dementia	No	Not reported
[49]	61 patients (49%)	71.8 (±8.3)	PD	Elderly	Tablets, ODT
[45]	1 patient (0%)	91	Alzheimer's disease	Cachexia, delirium, pulmonary aspiration, MRSA pneumonia	Tablets
[53]	52 patients (67%)	81 (±6.6)	Stroke	Elderly	Tablets, hard gelatin capsules

**Table 2** Population of included studies involving adults ( $\geq 18$  years) with neurological disorders with difficulties in swallowing solid oral dosage forms (n = 11)

ODT orally disintegrating tablet, PD Parkinson's disease, MRSA methicillin-resistant Staphylococcus aureus

\*Parkinson's disease patients, \*\*Patients without Parkinson's disease

Medicine optimization recommendations	n	%	
Systems for identifying, reporting, and learning from medicines-related patient safety incidents	3	12	
Medicines-related communication systems when patients move from one care setting to another	3	12	
Medicines reconciliation	0	0	
Medication review	9	35	
Self-management plans	3	12	
Patient decision aids used in consultations involving medicines	2	7	
Clinical decision support	2	7	
Medicines-related models of organizational and cross-sector working	4	15	
Total	26	100	

n number of Medicine optimization recommendations, % of Medicine optimization recommendations

## Intervention's Characteristics

**Table 3** Intervention categories according to the Medicine Optimization Recommendations (National Institute for Health and Care Excellence, [41]) of included studies involving adults ( $\geq$  18 years) with neurological disorders with difficulties in swallowing solid oral dosage forms (*n*=11)

In most studies (n = 7; 63.6%) interventions targeted patients [43–45, 48–50, 53]; only in one study the

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intervention was targeted to healthcare professionals [51]. In the other three studies interventions target both healthcare organizations or healthcare professionals or patients [46, 47, 52] (Table 4).

Table 4 Intervention details of included studies involving adults ( $\geq$ 18 years) with neurological disorders with difficulties in swallowing solid
oral dosage forms $(n = 11)$

Authors, years	Deliverers	How interventions were delivered	When interventions were delivered	Duration of intervention
Interventions ta	argeting patients			
[50]	Physician	Administration of screening instrument for difficulties in swallowing SODFs Physical examination (neurologi- cal) Administration of a swallowing	Outpatient medical consultation	Not reported
		questionnaire		
[43]	Physician	Physical examination	Hospitalization	3 days
[48]	Physician, nursing	Administration of a rating tool before and after changing from standard to dispersible dosage form of an anti-parkinsonian association	Hospitalization	1 week
[44]	Physician, nursing	Medication review and prescrip- tion	Hospitalization and at discharge	Not reported
[49]	Not reported	Administration of a rating tool before and after changing from standard to ODT of an anti- parkinsonian association Administration of a swallowing questionnaire	Outpatient medical consultation	3 weeks
[45]	Physician	Medication review and prescrip- tion	Hospitalization	Not reported
[53]	Physician, pharmacist, speech- language pathologist	administration of screening instrument for difficulties in swallowing SODFs Medication review	Hospitalization	Not reported
Interventions ta	argeting healthcare professionals			
[51]	Nursing	Direct observation of the medica- tion administration	Rounds of medication adminis- tration	55 min
Interventions ta	argeting healthcare organizations	and patients		
[52]	Physician, nursing	Administration of structured interviews Direct observation of the medica- tion administration Patient's records review	Hospitalization	1 week
Interventions ta	argeting healthcare organization	and healthcare professional		
		Direct observation of the medica- tion administration Professional training Administration of a knowledge questionnaire Analysis of pharmaceutical alternatives Establishment of a protocol		6 months
Interventions ta		, healthcare professionals, and patien	nts	
[47]	Physician, nursing, pharmacist	Establishment of a protocol Pharmaceutical interventions	Hospitalization, at discharge, and the shift	Not reported

SODF solid oral dosage form, ODT orally disintegrating tablet

In most studies (n = 8; 72.7%) physicians were responsible to deliver the intervention [43–45, 47, 48, 50, 52, 53], while nursing staff [44, 47, 48, 51, 52] pharmacists [46, 47,

53], and speech therapists were involved in five, three, and one study, respectively [53].

Interventions were mostly delivered to patients during hospitalization (n=7 studies) [43–45, 47, 48, 52, 53], or discharge and outpatient medical consultations (n=2 each) [44, 47] [49, 50]. For healthcare organizations or healthcare professionals, interventions were performed during work shifts (n=2) [46, 47] and rounds of medication administration [51] (Table 4).

Interventions were delivered in different ways with durations ranging from 55 min to 6 months; almost half (n=5; 45.5%) of the studies did not report this information (Table 4). Two studies used a swallowing capacity screening instrument. Buhmann et al. [50] administered the flexible endoscopic evaluation of swallowing (FEES) to assess the ability to swallow water and different shaped placebos vs. the usual anti-parkinsonian SODFs, and evaluated patients' dopaminergic response. Schiele et al. [53] employed a video endoscopy assessment to screen for swallowing difficulties and then conducted a medication review for all the participants. To report an adverse drug reaction, Casiano et al. [43] used a physical examination procedure. Two studies [44, 45] delivered interventions through both medication review and prescription. Chen et al. [51] and Kirkevold and Engedal [52] used the undisguised direct observation of the medication administration. This last authors also applied individual interviews to healthcare professionals and investigated patient's records. Two studies used the Unified Parkinson's Disease Rating Scale (UPDRS) motor subscore assessment before changing from standard to dispersible dosage form of two different anti-parkinsonian associations [48, 49]. In addition, Nausieda et al. [49] assessed which SODF was preferred by patients by means of a questionnaire. Questionnaires were also applied by Bennett et al. [46] to evaluate the knowledge acquired by healthcare professionals after training. This same study also analyzed pharmaceutical alternatives and established a protocol of medicines commonly prescribed for stroke. In the study of Garcia-Aparicio et al. [47] interventions were delivered according to a modified protocol of pharmaceutical formulations considering tolerable textures (pudding, honey, nectar, liquid) (Table 4).

#### Interventions' Outcomes Measures

At least 20 different outcomes were evaluated in the studies. Patients' clinical conditions were measured in three case studies: Casiano et al. [43] reported significant blood pressure control and hospital discharge; Gadit et al. [44] reported the need of percutaneous endoscopic gastrostomy (PEG) tube insertion in cases of swallowing difficulty, psychotropic medications review and hospital discharge; Regenold and Prasad [45] found improvements of patients' agitation levels, resolution of flailing and diminished babbling, and a decrease of the Cohen-Mansfield Agitation Inventory score (from 39 to 11).

The patient's swallowing of SODFs preferences was analyzed for five included studies. Schiele et al. [53] measured swallowing performance through the Penetration Aspiration Scale (PAS) and found 36% of patients describing difficulties in swallowing SODFs, even when texturemodified water (40%) and milk (43%) were used. Texturemodified water proved to be safer and more effective for swallowing; PAS score was higher for milk (1.5-2.5) when compared to texture-modified water (1.5-2.0). Authors also found that 21% of the modification of the prescribed SODFs were inadequate; of these, 47% could have been suspended, and 53% could have been switched to pharmaceutical or therapeutically equivalents. According to Garcia-Aparicio et al. [47] that assessed 134 different interventions for the adequacy of the prescription of SODFs patients' preferable texture was "pudding". In another study [50] using FEES, 28% patients with PD and 16% controls without the disease reported impaired ability to swallow four SODFs placebos differently shaped. Authors observed a significant association between patient's swallowing ability for each SODF and water and found capsules to be easiest to swallow; instead, the oval tablets were the most difficult. Overall, 73% of patients showed swallowing problems for one single dosage form, and 48% revealed water aspiration, suggesting a possible increased risk of aspiration to the administration of modified SODFs. Swallowing difficulties of SODFs were not associated with the dopaminergic response. Data regarding patients' formulation preferences followed by UPDRS motor subscore evaluation was provided in two studies. In one of them, all the patients preferred dispersible formulation [48], much more than the 45% of the patients who preferred orally disintegrating tablet (ODT) reported by other study [49].

Four studies assessed professional practices to optimize the use of SODFs. Bennet et al. [46] evaluated the knowledge acquired through a questionnaire and found an improved nurses' confidence in their ability to manage dysphagia, including the administration of oral medicines (Table 5). Chen et al. [51] analyzed 644 SODFs preparation and 577 SODFs provisions; of these, 22% were modified (42% in memory support units and 15% in standard units). The time spent on medication administration was higher when one by one tablet (mean  $91.61 \pm 51.75$  s) was delivered vs. crushed tablets (mean  $66.12 \pm 36.05$  s), whole tablets (without any modifications), and tablets delivered at the same time (mean  $54.84 \pm 45.39$  s). The study of Garcia-Aparicio et al. [47] described that 41% of the interventions mixed oral medication with foods aiming at swallowing promotion. Authors also found that 94% of interventions related SODFs prescription and administration of SODFs performed by the pharmacist were considered adequate. In another investigation, mixing SODFs with food was reported as very frequent (95%); significant reasons for its provision

Authors, years	Outcome measures	Outcomes recorded
[46]	a. Impact evaluation questionnaires on the practice after the education intervention	a. Improved nurses' confidence in their ability to manage dys- phagia, including the administration of oral medicines
[50]	a. Ability to swallow four differently shaped placebos	a. Impaired ability: patients 28%, and controls 16%
	b. Association between a patient's swallowing ability for each SODF and water	b. Capsules were the easiest to swallow while oval tablets were the most difficult; swallowing problems only for a single for- mulation, patients that showed aspiration of water 48%
	c. Patient characteristics	c. Higher disease severity was associated with more problems with swallowing SODFs, but PD patients with short disease duration (<2 years), low Hoehn and Yahr stage (1–2), and younger age (<70 years) were also affected (each at least in 20%)
	d. Dopaminergic response	d. Swallowing difficulties of SODFs were not associated with a lack of dopaminergic response
	e. Value of two swallowing screening questions for dysphagia of SODFs	e. Insufficient sensitivity 52% both, but fairly good specificity $6974\%$
[43]	a. Clinical condition	a. Control of the blood pressure and hospital discharge
[51]	a. SODFs preparation and provision	a. SODFs prepared 644 and SODFs provided 577; SODFs modified 22%: in memory support units 42% and in standard units 15%
	b. Time spent on medication administration	b. Delivered one by one (mean $91.61 \pm 51.75$ s); crushed tablets (mean $66.12 \pm 36.05$ s); whole (without any modifications), and together at the same time (not one by one) (mean $54.84 \pm 45.39$ s)
[48]	a. Patients' formulation preferences	a. Dispersible formulation 100%
	b. Patients UPDRS motor subscore	b. Improvement in UPDRS motor subscore of the patients 79%, deterioration of 1 point in 5,3% of the patients, and improvement in motor activity, primarily akinesia and stiffness 74%
[44]	a. Clinical condition	a. PEG-tube insertion given because of the swallowing dif- ficulty; psychotropic medications review; hospital discharge
[47]	a. Ideal texture for ingestion (considering the texture with the least tolerated consistency)	a. "Pudding"
	b. Interventions performed for the adequacy of the prescrip- tion of the medication, according to the texture tolerated by the patient	b. Swallowing facilitation by mixing the oral medication with food 41%, and by adding texture-modified water 59%; interventions considered adequate 94%, and interventions with some problem related to the administration/taking of the oral medication (unpleasant taste, negative oral intake, and asphyxia) 6%
[52]	a. Characteristics of patients and wards relating to the practice of mixing drugs in patients' food or beverages	a. Patients in regular nursing home units 11%, patients in spe- cial care units for dementia at least once 17%, and the practice was routine 95%
	b. Reasons for administering medicines covertly	b. Non-compliance 54%, a problem with swallowing 28%, and "to perform the necessary treatment" 10%
	c. Who decided to conceal the drugs	c. Nurses in charge 63%
	d. Documentation in patient records on covert medication administration	d. 40%
[49]	a. Patients' formulation preferences	a. ODT 45%, conventional tablets 20%, and no preference $35\%$
	b. Total UPDRS scores during the "off" and "on" states	b. Found no statistically significant differences in total UPDRS scores in the "on" and "off" states between the two formula- tions
	c. The mean amount of "off" time per 24 h, determined From the 3-day diary records	c. The mean (SD) "on" time was longer with ODT, 1.72 (0.35) days, than conventional tablets, 1.63 (0.36) days; the mean (SD) "off" time was significantly less with the ODT compared with the conventional tablets (0.31 [0.32] days vs. 0.39 [0.40] days)
	d. Monitoring adverse effects	d. Incidence of adverse effects was statistically similar between the two formulations

**Table 5** Intervention outcomes of included studies involving adults ( $\geq 18$  years) with neurological disorders with difficulties in swallowing solid oral dosage forms (n = 11)

Table 5	(continued)
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Authors, years	Outcome measures	Outcomes recorded	
[45]	a. Clinical condition	a. Improvement of agitation levels, resolution of flailing and diminished babbling, and a decrease of the Cohen-Mansfield Agitation Inventory score (from 39 to 11)	
[53]	a. Swallowing performance according to the PAS	a. Difficulties swallowing SODFs described by patients 36%, problems swallowing SODFs experienced by patients with texture-modified water 40%, and with milk 43%; SODFs increased PAS values in most of the patients (texture-modified water: 1.5–2.0; milk: 1.5–2.5)	
	b. Evaluation of the prescribed SODFs	b. Inadequate modification of prescribed SODFs 21%: could have been suspended 47% and switched to pharmaceutical or therapeutically equivalents 53%	

SODFs solid oral dosage forms, PD Parkinson's disease, UPDRS Unified Parkinson's Disease Rating Scale, PEG percutaneous endoscopic gastrostomy, ODT orally disintegrating tablet, PAS Penetration Aspiration Scale

were non-adherence (54%) and problems with swallowing (28%) [52].

None of the included studies reported costs or resource requirements.

## Discussion

To our knowledge, this is the first scoping review to systematically evaluated 11 observational studies on interventions targeting the management of solid oral pharmacotherapy for adults with difficulties in swallowing and neurological disorders in different healthcare settings.

Some systematic reviews evaluated specifically the use of SODFs in older adults with swallowing difficulties, but not with neurological disorders. Among these, some only aimed to describe interventions for improving use [26, 27] or the patient adherence to therapy [5]. In another systematic review, patients with neurological disorders and swallowing difficulties were analyzed, but not the interventions to use medications [4]. In a narrative literature review, Yetzer et al. [22] presented intervention strategies for safe SODFs management for patients with stroke, including tools for patient assessment, practice tips, and devices available to assist the patient and family. We found that most studies usually evaluate elderly patients with PD or dementia by means of medication review and medicines-related models of organizational and cross-sector working as intervention categories.

Older patients are known to have difficulty swallowing due to physiological decline, which can significantly affect the use of SODFs [54]. Fodil et al. [30], by assessing the staff observance of good clinical practices in 17 geriatrics units in 3 teaching hospitals, found that 30% of the elderly patients were unable to swallow SODFs. A recent systematic review suggested that the prevalence of difficulty swallowing of SODFs is approximately 14% among community-dwelling older patients [27]. Because the swallowing involves several central nervous mechanisms, neurogenic dysphagia [55] is prevalent in patients with neurological conditions [25]. It is estimated that it occurs in 84% of Alzheimer disease patients, in approximately 65% of acute stroke patients, and the prevalence rates vary, in dementia from 13 to 57% and PD from 35 to 50% [47, 55].

This aspect highlights the need for further interventions, mainly that target to reduce non-adherence to oral therapy, which can impair the management of the disease and consequent increase in morbidity and mortality [56]. Studies reported that patients (20% of aged care facilities and approximately 70% of the community) with swallowing difficulties skip their medicines due to this problem [57–59]. Also, the different characteristics of SODFs might impact the patient acceptability and potentially their medication adherence. 37% of a primary care general population (not exclusively neurological) reported difficulty swallowing SODFs [18], similar to 36% reported for analyzed patients with stroke and dysphagia [53]. In addition, the texture of the liquid used for swallowing SODFs can be revised and adjusted according to the patient's preferences, facilitating the process [47]. In another study, older outpatients with swallowing difficulties reported more likely to have problems related to tablets and capsules of large sizes than participants without dysphagia [19]. Similarly, in our review, three studies exploring PD patients' SODFs swallow preferences demonstrated that dispersible tablets [48], ODTs [49], or capsules [50] of anti-Parkinsonian associations were better approved by patients than whole tablets.

A recent cross-sectional online survey with PD patients (Eating Assessment Tool (EAT-10) [60]) revealed that multiple strategies for swallowing SODFS, including crushing tablets, or mixing it with food (e.g., yogurt or fruit juice) are effective [2]. These findings are agreement to those reported by Garcia-Aparicio et al. [47] in PD, dementia, or post-stroke patients, that found a rate of patients' acceptance of these strategies of over 40%. In Norway, for instance,

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mixing drugs in the food or beverages is a common practice in special care units for people with dementia according to Kirkevold et al. [52]. These strategic interventions are relevant because the pharmacotherapy must be adjusted to the patient's needs and preferences, which, if previously known, can optimize the use of SODFs. However, modifications should be carried out only after following pharmacist and medical practitioner authorization [7, 20, 61].

Medication review, aiming at optimizing the impact of medicines and minimize the number of medication-related problems, was the most common category of interventions. In this review, most patients of the included studies were older. Elderly, neurological disorders and polypharmacy are closely related, impacting directly on the use of SODFs in patients with swallowing difficulties and to plan the necessary interventions is important reviewing the prescribed medicines. Patients with difficulties in swallowing SODFs are more likely to experience medication errors than those without this problem in the same healthcare setting [17, 62]. Several of these errors are related to modification and should be a concern of healthcare organizations and professionals. In an online survey, 94% of the healthcare workers in aged care facilities across Australia modified medications to facilitate administration [13]. A qualitative interview study, also to inform professional practice, reported the views of community-dwelling older adults and their carers about SODFs modifications [11]. In this review, medication errors in neurologic disorders patients did not explicitly be evaluated. Only one included study reported inadequate modification for 21% of the prescribed SODFs and practice after the education intervention (Schiele et al., [53]).

The concealment of medicines in food or beverages is currently used in nursing homes. Kirkevold and Engedal [52] reported this procedure for 95% of patients, similar to the 100% found by another study [54]. Although this strategy can facilitate swallowing it can be inappropriate in some cases, thus requiring the review of de medication to improve the quality of clinical activities. Haw and Stubbs [63], for example, did not identify safety issues associated with the addition of medication to food or beverages when, in 97.1% of the cases in which this practice was necessary, the multidisciplinary health team discussed it previously. McDerby et al. [25] found a significant reduction in the proportion of inappropriate SODFs modification (from 24 to 0%) that was possible only after medication review.

Medicines-related models of organizational and crosssector working were also frequently reported in the included studies and refer to inter-organizational work that can enable the provision of continuous care during patient' use of the health services [41]. In this context, Fodil et al. [30], after assessing methods of SODFs modification and administration in geriatric units, and showing that they were mostly inappropriate, strongly suggests healthcare staff to reevaluate their institutional practices. Haw et al. [64] detected 26% of medication errors in the SODFs administration in two elderly long-stay wards in old-age psychiatric hospitals. The included study of Kirkevold and Engedal [52] found that routines for concealing drugs in patients' foodstuff was arbitrary, and practices were poorly documented in the patients' records. Additionally, researchers highlight that the time taken to administer SODFs modified medications should be longer compared to regular medications considering the higher complexity of the process [51]. These results would likely be different if cross-organizational works were developed. In addition, medication review benefits can be maximized when medicines-related models of organizational and cross-sector working are performed. [46, 47].

The significant prevalence of studies targeting patients during hospitalization in our review raises the question of which is the best strategy to deliver interventions, especially because only one study reported patient educational interventions on the use of SODFs. [47]. Moreover, ambulatorial patients with neurologic disorders are presumed to be unable to manage their oral medication, and swallowing difficulties are not a usual concern at hospital discharge. In a retrospective cohort study including stroke and hip fracture patients with dysphagia, the recommendations of SODFs use were omitted in 95% of the hospital discharge communications [65].

Interventions were performed in most cases by physicians; however, only swallowing difficulties and SODF preferences were evaluated. Only two studies developed protocols aimed at prescribers and nursing staff on the prescription and modification of SODFs for patients with swallowing disorders [46, 47]. Continuing medical education is a clear need as indicated by Sestili et al. [56], after finding no improvement in the prescription of hospital discharge SODFs for older people with dysphagia when comparing admission and discharge prescriptions. Conversely, a significant improvement (from 45 to 91%) on the safe modification rate of SODFs has been reported after nursing education interventions in an Australian medical oncology ward [66].

The investigation of multidisciplinary team procedures can provide important insights and enable planning actions for administering SODFs. Two included studies assessed patient records and nursing rounds in elderly hospitalized patients with swallowing disorders and recommended reevaluation of practices [30, 64]. Nevertheless, these investigations did not present intervention strategies for safe medication management as proposed for stroke patients [22, 46].

The rehabilitation nurse is charged with evaluating the patients' needs and developing strategies to assist them to manage their medications [22]. However, pharmacists may optimize the SODFs use in patients with swallowing difficulties. Although all healthcare professionals' input and expertise will be required, the pharmacist must take responsibility

for the task as a medication expert [11]. Wright et al. [14] performed a study on the responsibility of SODFs use optimization for hospitalized patients with dysphagia in the UK perspective and concluded that the most indicated professional is the ward pharmacist or the local medical information service. A recent Australian study reported factors affecting aged care facility workers in administering oral medication to residents with swallowing difficulties. The results indicated that the development of targeted interventions is needed for different groups of healthcare workers. Pharmacists can play an important role by providing professional support in different ways toward access to guides and resources [3].

We also found that most interventions were delivered using a swallowing capacity screening instrument, direct observation of the medication administration, individual interviews, and UPDRS motor subscore. Due to different intervention characteristics, a variety of outcome measures was reported. This is an important topic as it limits an extensive extrapolation of data and meta-analysis about the search questions.

This scoping review has some limitations. The search was limited to papers published in Roman characters and available in full-text, which might reduce the generalizability of this scoping review. Additionally, this overview reveals no consensus on the interventions carried out on the subject in health environments.

# Conclusion

The available published research about the interventions aiming at the use of SODFs in adults with neurological disorders and swallowing difficulties was mapped. Different professionals in different health settings applied various interventions. Unfortunately, many studies only assessed patients' preferences, risk of aspiration, or their ability to swallow SODFs. Implementing specific protocols for using SODFs aimed at the swallowing difficulties of this population is not a common practice; however, its implementation can facilitate professional practice and prevent harm to the patient.

Additional studies on interventions aimed at optimizing SODFs, especially those carried out by a pharmacist, are needed to support the safety and efficacy of oral therapy in this patient group.

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## Declarations

**Conflict of interest** The authors declare that they have no conflict of interest.

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