Title: Screening for, and overcoming, 'pill aversion' in community pharmacy using a novel educational tool: Hard pill to swallow?™

Abstract (250 words)

Background

Solid oral dosage forms (pills) are commonly dispensed but frequently patients struggle to take these (pill aversion). This is rarely identified or addressed in clinical practice. The KidzMed programme teaches children to swallow pills, to date it has not been used to support adults with pill aversion.

Objectives

- Assess in community pharmacy the acceptability of screening for pill aversion
- Test an educational leaflet tailored for adults to support with pill swallowing

Methods

Participants were recruited via pre-defined inclusion and exclusion criteria using convenience sampling at three Liverpool-based community pharmacies over a one-month period. A screening questionnaire was completed and adults >18 years identified with pill aversion (score of 6+ on the PILL-5 screening tool) supplied with an adapted educational leaflet from the KidzMed programme. Outcome was assessed via phone-call two weeks later. Institutional ethics reference (PBS/2023-23/01).

Results

Overall, 246 participants were screened, 9% (n=22) were identified as having pill aversion. There was an association with younger age and female gender. Follow-up showed that the leaflet was well received, participants found it useful, had changed their pill swallowing technique because of it, and shared this knowledge with others.

Conclusions

Pill aversion is an underexplored issue. The positive impact of the adapted leaflet in adults reflects the success of KidzMed for children. Further work is needed to confirm the association of age and gender with pill aversion, and determine translatability of the adapted leaflet to a wider audience and other healthcare settings.

Keywords

Solid oral dosage forms- pills- tablets- capsules- medication adherence- community pharmacy- patient education- swallowing difficulties

Background

Solid oral dosage forms i.e. tablets and capsules (colloquially referred to as pills and hereon after) are among the most common formulations prescribed [1]. This is due to their low manufacturing costs, taste-masking potential, ease of storage and patient acceptability profiles. However, on average ~20% of patients struggle to swallow pills thus affecting medication adherence and therapeutic outcomes [2]. In many cases this may not be due to dysphagia that warrants specialist referral and advice. Instead, patients suffer from presbyphagia (natural changes in swallowing associated with ageing also affecting pill swallowing ability), or cognitive pill aversion (fear or anxiety about choking when swallowing pills with no identifiable medical cause) [3,4].

Pill aversion is potentially an ageless problem as outlined in our review paper on this topic; however, it appears to be linked to several factors [2]. It is common in younger pill naive patients, females who have typically a smaller mouth cavity, patients with oropharyngeal crowding (e.g. large tongue), those with unpleasant past experiences such as choking or gagging, and polypharmacy where there is a high pill burden [5–7] . Despite this, it often goes unrecognized by healthcare professionals with patients adopting coping strategies including pill modification (such as crushing) and skipping doses, rather than disclosing and addressing the issue [8].

Until recently most work has focused on adults with dysphagia and teaching children to swallow pills. There is increasing acknowledgement that seemingly healthy adults may also need support. However, this

cannot be initiated unless pill aversion is identified. There are a variety of screening tools reported in the literature including the Sydney Swallow Questionnaire, Medicines Acceptability Questionnaire, EAT-10, SWAMECO, and PILL-5 [9–12]. These, along with bespoke questionnaires designed to meet the study aims and objectives are used in current literature. However, to date there is no single globally or nationally recognized screening tool that is recognized and used by healthcare professionals in practice to screen for and identify patients with pill aversion who warrant intervention. This is important as patients with pill aversion may be less adherent to their medication. This could be particularly problematic for aging populations, where chronic long-term conditions increase and this coincides with increased pill burden [13]. Polypharmacy is more common in this patient population, and non-adherence to medication is associated with higher all-cause hospitalizations and mortality [14,15]. This can lead to significant costs to healthcare systems, some of which could be avoidable, if screening and education techniques were available to first identify, and then support patients with pill aversion [16].

Techniques to improve pill swallowing include throat sprays, pill cups, verbal instructions, and different head positions, i.e., the pop-bottle method and the lean forward technique reported by Schiele et al [17]. The 6-step pop-bottle method and use of candy/ dummy pills underpins the KidzMed programme [18]. This validated training was designed to teach children as young as four years old to swallow pills at The Great North Children's Hospital, Newcastle-upon-Tyne (England). The initial pilot project showed the effectiveness of the programme on i) patient education as 21 children successfully learned how to swallow pills confidently) and ii) cost-savings which proposed annual savings of £42,000. Numerous hospital trusts in the United Kingdom (UK) are adopting this technique, and it is being disseminated globally [19–21]. It has been used to equip adult healthcare professionals in training and practice with the necessary knowledge to teach patients this skill, but using the original resources aimed at paediatric patients [22,23].

To date only one study has been conducted on this topic in the UK in adults over 65 years with and without dysphagia [9]. This work builds on existing evidence and will focus on adults 18 years or older without dysphagia. It aims to capture experiences of, and address using an adaptation of the KidzMed programme, pill aversion in 'healthy' adults in community pharmacy settings.

Objectives

- Assess patient experiences of pill swallowing in community pharmacies in the Liverpool region over a 4-week period through paper-based questionnaires.
- Support patients warranting intervention via provision of an educational leaflet tailored for adults outlining the key steps of the KidzMed programme.
- Explore patient views on the educational leaflet and its impact if any on their pill swallowing ability via a follow-up phone call two weeks after initial screening.

Methods

The TIDieR framework was used to aid with reporting of this study as per supplementary information 1 [24].

The specific details of the methodology are outlined below.

Ethical screening: University ethics was sought and granted (PBS/2023-24/01) with the study deemed minimal risk.

Questionnaire design: Questionnaires are a convenient and effective way to gather data, and the team decided to use paper-based questionnaires to ensure inclusivity of participants and avoid reliance on and the potential for technological failures during the study. Two questionnaires were developed by the research team, and these were validated by three pharmacists to ensure sense and fitness for purpose. The questionnaires were both designed to be short to encourage engagement with an expectation of maximum time of five minutes to complete.

The first questionnaire (supplementary information 2) was designed as a screening questionnaire to identify those with pill swallowing difficulties warranting intervention. This captured demographics (gender and age) that has been linked to pill swallowing difficulties in the literature, the PILL-5 questions of Nativ-Zeltzer et al., (table 1) as a validated means of identifying those requiring interventions[10]. Other questions were drawn from the Medicines Acceptability Questionnaire of Liu et al., to explore technique / approach to pill swallowing e.g. head position/ if they took liquids with their pills [9]. Liu et al also asked participants to rate perceived ease of swallowability of a range of tablets and capsules in diagram form. The team decided that to gain complete insight, it was important to show participants physical pills, as

such a pack of six placebos (candy/ dummy pills) was presented in a monitored dosage system as shown in Figure 1. Participants were asked to verbalize to the researcher which pills they would feel confident swallowing and those that they would not. The researcher noted this on their screening questionnaire. The researcher then calculated their PILL-5 score and those scoring 6 or more were deemed suitable for intervention i.e., provision of the educational leaflet.

Table 1. PILL-5 screening tool used to identify pill aversion and participants warranting intervention

Figure 1 Placebo pills (candy and dummy pills presented to capture perceived ease of swallowability of a range of pill sizes and shapes.

The KidzMed comic strip is aimed at children, parents and carers and was adapted to capture key elements of the technique that could be used in adults [18]. The adapted educational intervention was a leaflet entitled Hard pill to swallow?™ (figure 2). It was reviewed initially by the KidzMed team (EL, YT, NV) to ensure core components of the technique had not been lost. This was done using an iterative process of discussion and amendment until consensus was reached.

Figure 2. The educational leaflet designed for adult patients adapted from the KidzMed comic strip.

Follow-up was conducted in a similar approach to that of Craye et al [25]. A follow-up questionnaire (supplementary information 3) was designed to capture the views and impact of the educational leaflet. This was completed by the researchers who conducted follow-up via telephone contact two weeks after the initial screening and leaflet intervention. Questions included exploring if they had: read the leaflet; adopted the new techniques; found swallowing their pills easier as a result; found the leaflet useful; and told anybody else about the techniques. Having a set follow-up questionnaire ensured standardization across the different researchers at the point of follow-up.

Inclusion criteria: any adult aged 18 years or older attending the community pharmacies either to collect a prescription or as customer were invited to participate.

Exclusion criteria: people with a history of head/ neck/ throat cancer, diagnosis of dysphagia, or a condition that can precipitate swallowing difficulties such as Parkinson's' or Alzheimer's disease were exclude.

Participant recruitment: Researchers attended three community pharmacies during weekdays between 10am and 4pm for four weeks in November- December 2023. The superintendent pharmacist from the lead academics (AM and JNs') professional network served as the gatekeeper allowing the research team access to their pharmacy and patients.

Those eligible for inclusion were provided with a paper copy of the participant information leaflet (on the standard university template) by the research team to inform them about the study. This included a statement stating that the decision to participate or not would not affect their care or service provision from the pharmacy.

Participants who provided written consent viewed the dummy pills and completed a short (<5 minutes) paper-based questionnaire in the pharmacy's consultation room (supplementary information 2).

Intervention and follow-up:

Participants who scored 6 or more out of a total of 20 PILL-5 answers were categorised as having pill aversion and deemed suitable for intervention. If the participant scored <6 they were not considered to have any pill swallowing issues requiring intervention and participation was complete at this point.

For those warranting intervention, the researcher 1) provided them with an adapted educational leaflet from KidzMed (Hard pill to swallow?™), and 2) verbalised the key aspects of the leaflet with the participant. Follow-up data was obtained two weeks later by telephoning the participants. A maximum of three times were made (once on three consecutive days), if no reply was possible, participants were excluded from follow up. During the telephone call participants were asked to verbally consent to answer the pre-determined follow-up questions (supplementary information 3). Anecdotal comments were also recorded by the researchers.

Data storage synthesis:

All results from the paper-based screening questionnaires were inputted and collated by the researcher for those questionnaires into a shared Microsoft Excel document on the secure University network which was accessible only to the research team. Data was checked by a second independent researcher who did not enter the data. Paper copies of the questionnaires were stored in academic offices as per the University policy where they will remain until the point of publication after which they will be destroyed as part of confidential waste. Data was analyzed with the assistance of PM using MSExcel and descriptive statistics and a narrative synthesis prepared by the wider team.

Results

Participants screened and their reported experiences of pill swallowing:

Overall, 246 participants were recruited to the study and completed the screening questionnaire in full. Of these 76% (n= 187) took pills regularly. Most participants were female (53.2 % (n=131), 45.5 % male (n=112) and 3 did not disclose their gender. The average age of participants was 48.8 ± 18.9 (mean ± standard deviation (SD)) years, with 16 participants not disclosing their age, as per figure 3.

Figure 3. Participant demographics of the 246 patients screened for pill aversion in community pharmacies

PILL-5 scoring indicated that 224 participants (91 %) did not have pill aversion and therefore did not require intervention, whilst 22 (9 %) scored 6 or more and therefore had pill aversion and required intervention. The mean PILL-5 score for participants identified as having pill aversion (score 6+/20) was 7.1±1.5 (mean ±SD, range 6-10). PILL-5 scores indicated that pill aversion is associated with age (r= -0.2) and gender (r=0.3). There were more younger patients than older patients who had pill aversion ; (8/42 = 19 % in the youngest age bracket 18-29 years V 0/8 in the 80–89-year bracket), and females had a higher PILL-5 score than males as per figure 4.

Figure 4. PILL-5 scores (x/20) based on gender

Patients reported a variety of techniques they adopt to aid pill swallowing although most swallow their pills with water (n= 222 (90.2 %)), other methods include: putting the pill in the back of the mouth n = 66 (26.8 %), tipping their head back n=104 (42.3%), taking with food n= 12 (4.9 %), or swallowing the pill on its own with no liquid or food n= 30 (12.2 %). More concerning reports were physical modifications of pills dissolving in water, splitting in half, and chewing by n=24 (9.8%) of PILL-5 responses. In addition, free-text responses also captured: a person that chewed their aspirin dispersible "then slushed water around their mouth"; another that halved their paracetamol tablets; another "halves large round tablets if they have a score mark"; and another that "cuts most tablets in half".

Participants reported a range of concerns and preferences associated with pill swallowing including that they occasionally give them heartburn, small pills get lost, large pills get stuck, difficulties with round pills and large capsules, holding pills in the mouth until they become sticky and difficult to swallow, and preference for coated compared with uncoated pills.

When asked about perceived swallowability of the placebo pills (figure 1), most of the participants (n= 156) reported that they would not have any difficulties with the placebo pills. For those that identified placebos that they may struggle to swallow, it was assumed that they would also struggle with any size greater than this (table 2). For both shapes, larger sizes appeared to be associated with lower perceived swallowability for both round tablet-like and capsule placebos.

Table 2. Placebo pill properties and their perceived swallowability based on number of participants that reported possible difficulty swallowing these

Views of participants identified with pill aversion who received the educational leaflet

Most of the intervention group (19 / 22 (86 %)) were captured at follow-up (two weeks later). The remaining three participants could not be contacted by the research team. Of the 19 participants captured, all reported that they found the leaflet useful. Most had read it (18/19, 94.7 %) and stated that it had changed the way they take their pills as a result, and they now found this easier (14, 73.6 %). They found the leaflet helpful for others in their household too, including children, and over half (11, 57.8 %) had shared the leaflet with others in their social network. Some additional anecdotal comments noted during the call by the research team have been captured in figure 5.

Figure 5 Feedback comments from the intervention group that received the educational leaflet at two-week follow-up

Discussion

Key findings:

This study shows that it is possible to screen, identify, support, and follow-up patients with pill aversion in community pharmacy. Pill aversion was identified using the validated PILL-5 screening tool and had a prevalence of 9 % (22/246 participants). It was more common in females and younger participants. A range of coping techniques were reported adding further evidence to the literature. Larger sized pills had a higher perceived swallowing difficulty. The educational leaflet (Hard pill to swallow?™) was effective at improving pill swallowing technique and overcoming pill aversion. This is the first demonstration of using an intervention to reduce pill aversion in adults.

Findings in the wider context

This was an observational study conducted in community pharmacy. The pharmacies were selected due to their convenience, and they were known to the research team. They were all part of the same small chain of pharmacies (study took place in 3/5 of the pharmacies- those with the biggest footfall to ensure a reasonable number of participants). Similar studies have taken place using the same or a greater number of community pharmacies (3-10) but with fewer participants to the study presented here (Liu et al., N=156, Arnet et al., N= 66, Craye et al., N= 111 v in this study N= 246) [9,12,25].

GP surgeries and community pharmacies are effective locations for patient engagement with positive health interventions including screening and identification of pill aversion. This has been attributed to their good professional relationships both within their teams and with their patients [26]. Current literature refers to patients' likelihood of disclosing pill aversion to those known to them. If the healthcare teams in these settings, ask specifically about this as advised by Marquis et al., perhaps this will facilitate improved detection and intervention [8]. It is also important to consider the accessibility of community pharmacy including in socially deprived areas as described by the 'positive pharmacy care law' [27]. Community

pharmacy is viewed in many countries as the front door to accessing healthcare. Campaigns such as the annual UK National Pharmacy Association campaign 'ask your pharmacist' week, and enhanced services such as smoking cessation, vaccinations, and prescribing, are directing the public to the pharmacy first [27,28]. Pharmacists are often described as the 'experts in medicines', therefore they are well placed to enquire about pill aversion. How this should be done remains unclear, however, asking the initial question allows this conversation to flow. It is widely-noted that patients do not tend to offer this information to healthcare professionals hence enquiry is necessary [4,8,25,29–31]. This can involve behavioural focused questions such as that of a Dorman et al., "What thoughts do you have when you look at your pills?", or Craye et al., "Do you experience extra effort when swallowing your pills?" or use of a screening tool as per this and several other studies.

As detailed earlier, there are several validated self-reporting screening tools being explored in studies relating to pill swallowing. These are of various lengths Messerli et al.,'s SWAMECO = 30 items, [32] Souza et al., Eat-10= 10 items [11], Nativ-Zeltzer et al.,'s PILL-5 = 5 items [10]. Patients often visit community pharmacies with a goal of purchasing something, seeking advice, collecting medication, or for a specific pharmacy service. They do not expect and perhaps wish to spend unexpected additional amounts of time in the pharmacy participating in research. Therefore, the team felt that it was important for this study that a concise but specific screening strategy was used to facilitate uptake – PILL-5 lent itself to this. We have used it successfully with student pharmacists and found it an efficient way for self-reflection of pill swallowing experiences [22]. Some additional questions were included to enrich the data and conclusions regarding pill aversion as described in the methodology and per supplementary information 2.

Pill aversion prevalence in this study (9%) aligns with that of previously reported studies including that of Liu et al., also conducted in the UK (mean prevalence 9.4% in 156 participants) [9] . Direct comparisons between the screening tools are not possible but many have a cut-off score that defines pill aversion- in the case of PILL-5 a score of 6/20 is used. Consideration should be given to variations in reported prevalence, age, and number of participants. It appears that there is an association with higher reported prevalence of pill aversion in studies where a broader age group is included and those with more participants. For example, there is higher prevalence reported in the studies of Souza et al., (17% in 439 participants aged 20-84 years), and Lau et al., (14.1% in 369 participants 18 years and older), compared to this study despite inclusion of similar participants (246 participants 18 years and older). It reinforces

reflections on lack of diagnosis and enquiry about pill swallowing difficulties and appears that the more patients that are asked about this the more cases are found.

In terms of other characteristics, it is noteworthy that most of the participants in this study were regular pill takers (76%) thus not pill naïve. However, as per other studies we noted an association between younger age (*r*= -0.2), female gender (*r*=0.3) and pill swallowing difficulties. Younger patients have perhaps not learnt the art of pill swallowing and may have less experience than older patients who are more likely to have regular medication for long-term conditions [30]. Our review paper on this topic also noted a higher number of females reporting pill aversion than males, with Marquis et al., linking this to anatomical differences – smaller mouth cavities, pharynx and larynx differences in females [2,8].

With regards to coping techniques to manage pill aversion, the reported approaches were very similar to those captured elsewhere [2] . These included drinking more water, taking with food, different approaches to pill localization and head positions, and most concerning skipping doses and medication modification which can contribute to poorer therapeutic outcomes. Reported pill characteristics and perceived acceptability also echoed that of existing publications [33]. Capsules are often considered preferable as per Ibrahim et al., who also linked this preference to females [34], but also favoured in studies by Overgaard et al., [35] Fields et al.,[36] and Parraga Acosta et al.,[37] . There was also a preference for coated pills over uncoated, this reflects the studies of Uloza et al., and Yamamoto et al., [38,39]. Coating is widely used in pill manufacturing to overcome the bitter taste of active pharmaceutical ingredients and to improve pill smoothness hence swallowability. Size also matters as demonstrated here and several other studies report on larger pills being difficult to swallow [8,36,39]. However, they can also be too small (as reported by Fields et al., <4 mm can be problematic and our participants) resulting in lack of sensation in the mouth, or difficulty handling, thus alternative dosage forms like mini-pills may not necessarily be the answer [33,36,40]. It is difficult to determine swallowability of pill shapes or sizes without asking participants to physically swallow the pills, but this study captured perceived swallowability of placebo pills (figure 1). The findings are reflective of the above studies, with larger size for both round and capsule-like placebos having a lower perceived swallowability.

Regardless of pill properties, as per Forough et al., once pill aversion is identified the priority should be on restoring and then maintaining swallowing ability [5]. How this happens varies, but the literature reports the following as key interventions to overcome pill aversion: advice on postural adjustment using the "pop-bottle method" and "lean forward technique" [17,18,22,25,41] ; behavioural interventions [42], and changing to an alternative dosage form if postural adjustments prove unsatisfactory [25]. Craye et al., similar to this study provided patients with an information leaflet documenting postural adjustments outlined above [25]. This study however is the first example of using the adapted version of the validated KidzMed programme in adults in clinical practice [18]. The participants were guided through the technique by the researcher ensuring their understanding and providing a supportive management plan to overcome their pill aversion using the educational leaflet to aid this. As noted by Craye et al., most patients with pill aversion can be managed this way rather than pursuing formulation switches [25]. This demonstrates that the technique is effective, and this was demonstrated at follow-up. Like Craye et al., our educational leaflet proved popular with the participants and achieved its goal – aiding pill swallowing. It also positively impacted on others through the participants sharing the information. Therefore meeting the unmet need for education of both patients and practitioners regarding action to take if pill aversion is experienced and implementation of effective interventions.

Implications for practice and policy

The findings show the promising impact of a simple intervention to screen for, identify and support people with cognitive pill aversion in healthy adults in a community pharmacy setting. This is important as managing pill aversion could support medication adherence, which is linked with higher levels of all-cause hospitalizations and mortality, higher expenditure for health systems and may be particularly problematic for jurisdictions with older people who use multiple medicines. An intervention that is simple and could be delivered at scale across thousands of pharmacies, in socioeconomically deprived communities, could support medication adherence and therefore have a positive impact on health outcomes, reduce hospitalization and health expenditure [14–16,43]. However, though a framework for implementing interventions in community pharmacy settings exists, there is limited recent work exploring how medication adherence can be supported in pharmacies practically that reflects current modes and demands of pharmacy practice (i.e., increased workload, hub and spoke dispensing models, online pharmacies) [44,45]. Further work is therefore needed around the feasibility of implementing a screening and intervention service in pharmacies which targets problematic pill aversion.

Strengths and weakness

There are several ares of strength to the work presented here. The study is the first of its kind using an adapted version of the validated educational leaflet of KidzMed for adult patients (Hard Pill to Swallow?™). There is no gold standard screening tool, however, validated tools were used in the screening questionnaire and proved effective in identifying pill aversion in the participants further confirming the limited body of evidence on this topic. The positive response from participants demonstrates that efficient interventions can have a real impact on patients in clinical practice i.e., asking about pill swallowing – and addressing issues with a leaflet.

There are some weaknesses, although the findings around association between female gender and younger age and pill aversion reflect the findings of others, widespread data on this is limited hence this should be interpreted with caution. Whilst the health and socioeconomic impact of pill aversion (and the impact this has on non-adherence) in older adults with polypharmacy could be significant, this may be over-estimated [14–16]. This study used an unrepresentative, small sample which means it is subject to recruitment bias. The smaller number of older patients with pill aversion may be explained by more experience of using pills to manage multiple conditions, as patients are exposed to using medications, they are less likely to experience aversion to it – drawing on the underpinning theory of desensitization therapy [46]. Perhaps those patients were unable to present to the pharmacy, or classed themselves as having dysphagia without official diagnosis, therefore were excluded at the point of recruitment [47]. Thompson et al., further consider health-seeking behaviour and link this to younger age so perhaps these participants are more likely to present to the pharmacy therefore be included in the study [48]. They also considered gender and concluded that females are more likely than males to engage with healthcare potentially explaining why more females were recruited to this and many other similar studies. It could be a case of the more you look the more you find as alluded to in the discussion section. Further work is therefore needed to explore pill aversion in older adults and males using alternative methods for recruiting participants to reach a more coherent conclusion.

Conclusions

This study demonstrates that it is possible to screen and identify pill aversion in community pharmacy using short paper-based, validated questionnaire. Participants were supported in improving their pill swallowing ability using an adapted educational leaflet (Hard pill to swallow?™) outlining the key steps of the KidzMed programme. This is the first time the adapted leaflet has been used in adults, and only the second example of pill aversion screening in the UK in a broader patient population (18+ years v 65 years+)[9]. Follow-up is important to ensure that pill swallowing ability has been restored and is maintained. The leaflet was effective in overcoming pill aversion in identified participants. The study also facilitated discussion about pill aversion between participants and their wider circle- breaking down barriers about this being something to hide. Further work is needed to confirm that the findings relating to younger age and female gender are true, and to test that the questionnaires and leaflet are suitable and transferable to community pharmacy as a wider sector in addition to other healthcare settings.

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