Running head: CONSUMER-FACING MEDICATION SAFETY TECHNOLOGY

Usability and feasibility of consumer-facing technology to reduce unsafe medication use by older adults

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ABSTRACT

Background: Mobile health technology can improve medication safety for older adults, for instance, by educating patients about the risks associated with anticholinergic medication use.

Objective: This study's objective was to test the usability and feasibility of Brain Buddy, a consumer-facing mobile health technology designed to inform and empower older adults to consider the risks and benefits of anticholinergics.

Methods: Twenty-three primary care patients aged ≥60 and using anticholinergic medications participated in summative, task-based usability testing of Brain Buddy. Self-report usability was assessed by the System Usability Scale and performance-based usability data were collected for each task through observation. A subset of 17 participants contributed data on feasibility, assessed by self-reported attitudes (feeling informed) and behaviors (speaking to a physician), with confirmation following a physician encounter.

Results: Overall usability was acceptable or better, with 100% of participants completing each Brain Buddy task and a mean System Usability Scale score of 78.8, corresponding to "Good" to "Excellent" usability. Observed usability issues included higher rates of errors, hesitations, and need for assistance on three tasks, particularly those requiring data entry. Among participants contributing to feasibility data, 100% felt better informed after using Brain Buddy and 94% planned to speak to their physician about their anticholinergic related risk. On follow-up, 82% reported having spoken to their physician, a rate independently confirmed by physicians.

Conclusion: Consumer-facing technology can be a low-cost, scalable intervention to improve older adults' medication safety, by informing and empowering patients. User-centered design and evaluation with demographically heterogeneous clinical samples uncovers correctable usability issues and confirms the value of interventions targeting consumers as agents in shared decision making and behavior change.

Keywords: Medications; information technology; shared decision making; patient safety; user-centered design; anticholinergics; human factors engineering; behavioral informatics; mobile health (mHealth); digital health (eHealth)

INTRODUCTION

In the "new era of patient engagement,"[1] interventions to improve the quality and safety of healthcare target not only the clinician, but also the patient, their family, and their social networks.[2] Contemporary decision aids and shared decision-making tools for patients leverage mobile and web technologies, including app-based or online risk calculators and patient portals.[3,4] These technologies are part of the broader landscape of consumer health information technology and mobile health (mHealth), in which a multitude of digital health applications have been developed to directly assist patients and their advocates in achieving health goals and promoting behavior change.[5] The work reported here extends consumer-facing mHealth to address medication safety among older adults prescribed high-risk medications. Specifically, we tested the usability and feasibility of Brain Buddy, a consumer-facing mHealth application designed to improve awareness and identification of potentially harmful anticholinergic medications and ultimately reduce their use among older adults.

Consumer-facing medication tools

Recently, digital medication related decision aids have seen increased use, particularly mobile applications supporting medication adherence.[6] Among older adults with chronic comorbid diseases, consumer-facing medication technologies may increase medication adherence and improve self-management,[7,8] but researchers have called for increased research to demonstrate the usability, feasibility, and effectiveness of these technologies across patient populations.[6,9,10] Additionally, research is needed to design and evaluate mHealth systems that improve not only medication adherence for chronically ill individuals, but also facilitate medication safety for broad populations, such as older adults.

Risk of harm from anticholinergic medication use by older adults

Prolonged use of anticholinergic medications by older adults is associated with long-term cognitive impairment, strongly evidenced by dose-response relationships between anticholinergic exposure and incident mild cognitive impairment and dementia[11-13] as well as brain atrophy in chronic anticholinergic users.[14] Consequently, multiple organizations including the National Academy of Medicine and the American Geriatrics Society recommend against older adults' use of anticholinergics.[15-17] Nevertheless, studies report that 20-50% of older adults use prescription anticholinergics and estimates sometimes exceed 80%.[18-20] A 2017 study reported anticholinergic use by 65% of Medicare beneficiaries.[21] Older adults also use over-the-counter (OTC) anticholinergics to relieve symptoms including insomnia, diarrhea, and pruritus, among others.[22-25]

Testing Brain Buddy, consumer-facing mHealth technology for medication safety

To reduce older adults' use of anticholinergic medications, we designed Brain Buddy, a consumer-facing mHealth application to inform and activate older adults to initiate dialogue with a clinician regarding the risks and benefits of their anticholinergic medications. The application directly targeted anticholinergic users, rather than prescribers or pharmacists, for two reasons. First, to our knowledge, all prior interventions to reduce anticholinergic use targeted only clinical professionals, with varying success.[26-30] Second, recent work demonstrates the potential of consumer-facing interventions for medication safety. Notably, direct-to-consumer educational materials in the EMPOWER and D-PRESCRIBE randomized trials eliminated or reduced benzodiazepine use in up to 43% of older adults.[31,32]

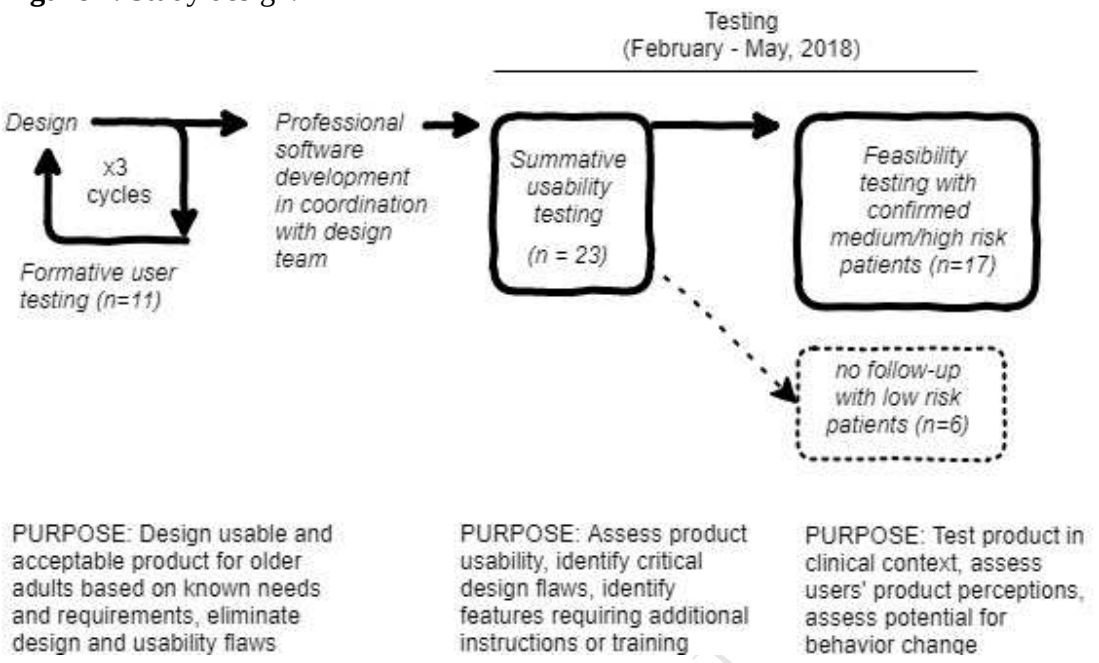
Brain Buddy was designed to address the user needs and requirements we documented in a prior investigation of anticholinergic users. That investigation found that older adults were unaware of the risks of using anticholinergics; would consider changing to an alternative treatment; and often viewed their physician as the primary source of medication information and decision making.[33] These findings suggested the potential for an intervention targeting awareness and behavioral activation among patients (consumers).

This study's objective was to test Brain Buddy for usability and feasibility with older adult anticholinergic users. We expected that the iterative, user-centered design of Brain Buddy would result in acceptable self-reported and performance-based usability. We also expected participants using Brain Buddy would initiate conversations with their primary care provider regarding anticholinergic risks.

METHODS

The study involved cross-sectional usability and feasibility testing of Brain Buddy with older adults. Twenty-three participants performed usability tests and a subset of 17 participants with medium or high anticholinergic risk contributed feasibility data (Figure 1). The study was approved by the Indiana University Institutional Review Board and occurred February-May, 2018. Testing was preceded by a roughly one-year period of iterative design and formative usability testing.

Figure 1. Study design.



User-centered design and formative testing

Brain Buddy was designed at the Brain Health Patient Safety Laboratory by a professional design team led by faculty with expertise in user-centered technology design and medication safety. The design team used an iterative, user-centered design approach, meaning empirically derived user needs and requirements were translated into prototypes, which were tested with intended end-users and redesigned over multiple rounds.[34]

The design team met weekly for approximately one year. Design work evolved from concepts and sketches, to flow diagrams with screenshot mockups, to a high-fidelity interactive prototype running on a mobile device. Design decisions were informed both by prior research on anticholinergic use and usability principles for older adults.[35-37] For example, Brain Buddy used linear navigation, large fonts, and minimal scrolling. The team consulted the risk visualization literature[38-40] to identify multiple ways to communicate anticholinergic risk, then comparison-tested the alternatives.

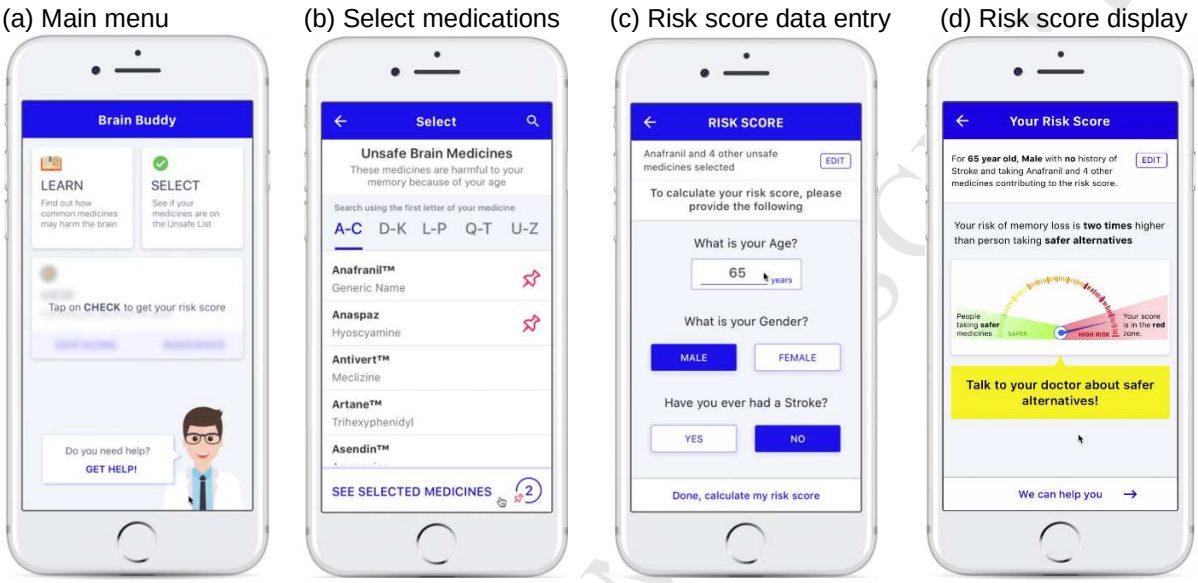
A staff user experience designer performed three rounds of formative usability testing with a total of 11 older adults (3-4 users per round). Participants were shown paper visualizations, screenshots, and educational content in all rounds. In Rounds 2 and 3 (n=8) they also interacted with a 5.5-inch Android Pixel XL phone running a prototype on the Marvel app simulator (marvelapp.com). Participants were probed to explain their understanding of the visualizations, offer feedback, and use the prototype for a set of scripted tasks while thinking aloud, with occasional follow-up probes. A similar procedure is described elsewhere.[34,41] Findings from each round of formative testing were used to further refine Brain Buddy; for example, the ultimate design used an analog temperature gauge to display risk, as this was the best understood visualization. The final design is described next.

The Brain Buddy application

For usability and feasibility testing, participants used a professionally developed version of Brain Buddy, implemented as a native Android mobile app. Screenshots in Figures 2 and 3 illustrate Brain Buddy functionality, which included: onboarding tutorial; home screen (Figure 2a); educational content about anticholinergic medications and risks associated with their use (Figure 3a); search, browse, and selection of medications from a list of definite anticholinergics (Figure 2b); data entry to calculate a personal risk score (Figure 2c); risk score visualization (Figure 2d); and a risk score report that can be saved and shared. Brain Buddy's educational content included three animated videos (Figure 3b-d), created and produced for Brain Buddy by the design team in collaboration with a digital storyteller and professional illustrator. Each video tells the story of an older adult (with variation in sex, race, and Hispanic origin) who learns about anticholinergic medications, then consults with a physician or pharmacist about their personal risk and safer alternatives. Videos range in duration from 3.5-4.5 minutes and address multiple

128 symptoms treated by anticholinergic medications, potential risks of anticholinergic use, the
129 availability of alternatives, and the importance of consulting with a clinician.

130 **Figure 2.** Example screen captures from the Brain Buddy application.



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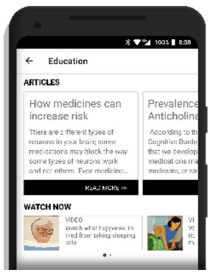
132 **Figure 3.** Screen captures of Brain Buddy education screen and custom-made educational
133 videos.



a) Videos (b-d) are accessible from Brain Buddy's Education screen.

Videos feature a) White, b) Latino, and c) Black main characters

a) Fred (and Albert, his friend)

b) Roberto (and Diane, his daughter)

c) Rose (and Emma, her pharmacist)

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Participants and setting

Participants were older adults with a scheduled primary care appointment with one of seven primary care providers at Eskenazi Health, a large urban community safety net health system in Indianapolis, Indiana, USA. Patients were included if they were aged 60 years or older and were prescribed at least one of the 13 commonly prescribed anticholinergics (Appendix A) in the prior three months. These medications account for most prescription anticholinergics in this patient population. Individuals were excluded if they resided outside the county or in a nursing home, did not have access to a telephone, reported a terminal illness, reported being treated for substance abuse, or scored 3 or lower on the six-item screener for cognitive impairment.[42] Participants were enrolled during the scheduled study period, with the goal of enrolling approximately 20 individuals, a target we deemed high for usability testing[43,44] and typical for feasibility testing of a behavioral intervention.

Potential participants were identified by review of medical records in the regional health information exchange, using a query specifying age, next appointment, primary care provider, and medication dispensing records. Phone calls were then placed by the university's research recruiting service to establish interest in the study and perform eligibility screening. A study research assistant contacted eligible individuals to arrange a meeting at the clinic on the day of their upcoming appointment. Participants were instructed to bring their medications with them.

Procedure and data collection instruments

Patients were consented in the clinic or exam room, then took part in a usability test and semi-structured pre-encounter interview lasting approximately 30-45 minutes combined, before being seen for their visit.

The usability test had the following steps: a) guided practice; b) observed actual use with personal data; and c) self-report usability evaluation. Guided practice consisted of a set of five tasks performed by the participant for the first time: Log in; Access education; Select medications; Obtain risk score; View risk report. The research assistant delivered verbal instructions to complete the task and what information to enter into the application. During actual use, participants were instructed to use Brain Buddy from beginning to end, entering their personal medication and demographic data to produce a personal anticholinergic risk score. When participants were deemed unable to progress on their own, they were prompted in progressive order with a question ("Is there something unclear on this screen?"), then verbal instructions (e.g., "You can tap on 'view report' to see your report"), then an offer to demonstrate ("Do you want me to show you and you repeat?").

The research assistant recorded performance-based usability observations on a structured observation instrument, noting for each task the user's behaviors and utterances in the categories: completion; mistakes; efficiency; assistance needed; emotions; and other. Participants then rated usability of the entire application on a researcher-administered paper survey using a modified System Usability Scale (SUS).[45] SUS is a well validated 10-item questionnaire with a five-point response scale from strongly disagree (1) to strongly agree (5). The modified version contains rewording of several items for ease of understanding by older adults.[34,41]

During the ensuing pre-encounter interview, participants who received a medium or high anticholinergic risk score when using Brain Buddy were given an informational Conversation Starter brochure about anticholinergics and encouraged to talk to their physician about anticholinergic risk. They were then asked whether they felt better informed about medications that may be unsafe for them and whether they planned to talk to their physicians about

potentially unsafe medications. Finally, they received an after-visit form for their physician to complete. The after-visit form was a 1-item questionnaire asking the physician whether, during the appointment, they had discussed with the patient medication safety related to the listed anticholinergic medications. Participants who received a low anticholinergic risk score for any reason, including software malfunction (a fault in the code) in two cases, did not receive a Conversation Starter and after-visit form and were not further interviewed.

Following the visit, the research assistant collected after-visit forms from physicians and attempted to contact participants by phone in the ensuing 24 hours for a post-encounter interview. Post-encounter interviews asked participants whether (and how) they discussed medication safety with their physician on the day of the visit and whether (and how) they had discussed medication safety with anyone else. Research staff also collected demographic information by phone. At the end of the study, participants were mailed a $20 gift card.

Analysis

Descriptive statistics were calculated on observed performance-based usability indicators, SUS items and scale score, and attitudes and behaviors self-reported by patients and their physicians. We defined acceptable subjective usability as above-average SUS scale scores relative to national norms, i.e., a score > 68.[46,47] For performance-based usability testing we used a cut-off of 70%. Quantitative data were exported from secure research software (REDCap), cleaned in Microsoft Excel, and analyzed in IBM SPSS V25. Qualitative researcher notes from usability sessions and interviews were examined for illustrative examples but not systematically analyzed.

RESULTS

Of those individuals reporting demographics, mean age was 67.6 (SD = 7.8, range 60-85), 61% were female, and 54% identified as Black or African American and 31% as White. Participants reported being insured by Medicare (69%), Medicaid (38%), or other public insurance (23%), with 38% insured by multiple plans. About one-fourth (23%) had not attained a high-school diploma and another 23% had Master's or professional degrees; the rest had a high-school diploma (15%) or some college or vocational training (46%). The majority (69%) had an annual household income less than $25,000 and 92% less than $35,000.

Usability

Performance-based usability indicators from the 23 usability test participants are reported for each of five tasks in Table 1. Every study participant was able to complete every task. Most individuals completed the tasks without mistakes, although 46% of participants made at least one mistake when selecting medications from a list. For example, a participant with hand tremors accidentally tapped a medication and had to remove it. Mistakes were also made by 25-30% of participants when accessing education and entering risk data. Examples of mistakes were: tapping icon or header to activate a link, not the link itself; accidental selection of a medication; attempting to proceed to the next screen before completing all risk-related data entry (this anticipated error launched a pop-up error message).

At least one-quarter of individuals were observed to pause or hesitate during the education, medication selection, and data entry tasks, signs of inefficiency in product use. In most cases, tasks were completed without assistance or with verbal encouragement.

Table 1. Observed usability indicators by task (n=23).

Usability element, N (%)	Tasks				
	LOG-IN	EDU-CATION[a]	SELECT MEDS	ENTER RISK DATA	VIEW RISK SCORE
Completion					
Finished task	23 (100)	8 (100)	23 (100)	23 (100)	23 (100)
Could not do it / gave up	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Mistakes					
No mistakes	21 (91)	6 (75)	13 (54)	16 (70)	22 (96)
Mistakes / had to redo or undo	2 (9)	2 (25)	11 (46)	7 (30)	1 (4)
Efficient use					
Quick / fluid work	22 (96)	6 (75)	14 (61)	15 (65)	21 (91)
Pauses / delays / hesitation	1 (4)	2 (25)	9 (39)	8 (35)	2 (9)
Assistance needed[b]					
None needed	20 (87)	5 (62)	9 (39)	14 (61)	22 (96)
Needed encouragement	3 (13)	2 (25)	6 (26)	5 (22)	1 (4)
Needed more instructions	0 (0)	3 (37)	10 (43)	8 (35)	0 (0)
Needed demonstration	0 (0)	0 (0)	3 (13)	1 (4)	0 (0)
Emotional response[c]					
Satisfied / smiling / nodding	22 (96)	6 (75)	18 (78)	20 (87)	19 (83)
Upset / frustrated / mad	1 (4)	2 (25)	4 (17)	2 (9)	4 (17)

Underlining indicates < 70%. LOG-IN = log in and get started; EDUCATION = read and view educational content; SELECT MEDS = select medications from a list; ENTER RISK DATA = enter age, gender, stroke history; VIEW RISK SCORE = view computed risk score and risk report. [a]The education task was not mandatory for those who viewed educational materials

during the guided practice session preceding the test. [b]An individual may have received multiple kinds of assistance. [c]If observed.

The mean usability score on the SUS was 78.8 and the median was 82.5 (SD = 15.7, range 37.5-97.5). The distribution of SUS scores was skewed left (skewness = -0.91, standard error = 0.48) but marginally normal. SUS norming data suggest 80.3 as the cut-off for an "A" grade, corresponding to the top 10% of scores from over 500 evaluations.[46,47] Brain Buddy's SUS score falls into the "Good" (mean SUS = 71.4) to "Excellent" (mean SUS = 85.5) range with respect to adjective ratings reported in Bangor and colleagues' analysis of 959 evaluations.[47] Table 2 reports participant responses on the ten SUS items. Items corresponding to ease of use had higher ratings, whereas intention to use and learnability ratings were slightly lower.[48]

Feasibility

Six of the participants in the usability test received a low anticholinergic risk score, either as a result of software malfunction, because they were no longer using anticholinergics, or in one case because the participant did not correctly input their medications. These individuals were not asked about their attitudes and behavior with respect to anticholinergic medication risk. The remaining 17 who received a medium or high risk score reported feeling better informed (100%) and planning to talk to their physician about anticholinergic medication risks (94%) (Figure 4). In a follow-up interview after their clinic visit, 82% of these 17 reported having indeed talked to their physician and 35% also spoke to a family member or nurse. For 11 of these 17 participants, a physician completed the post-visit form indicating whether they had talked to the patient about their anticholinergic medications, with nine of 11 (82%) indicating they had. Although not systematically assessed, several individuals volunteered their plans to replace an anticholinergic

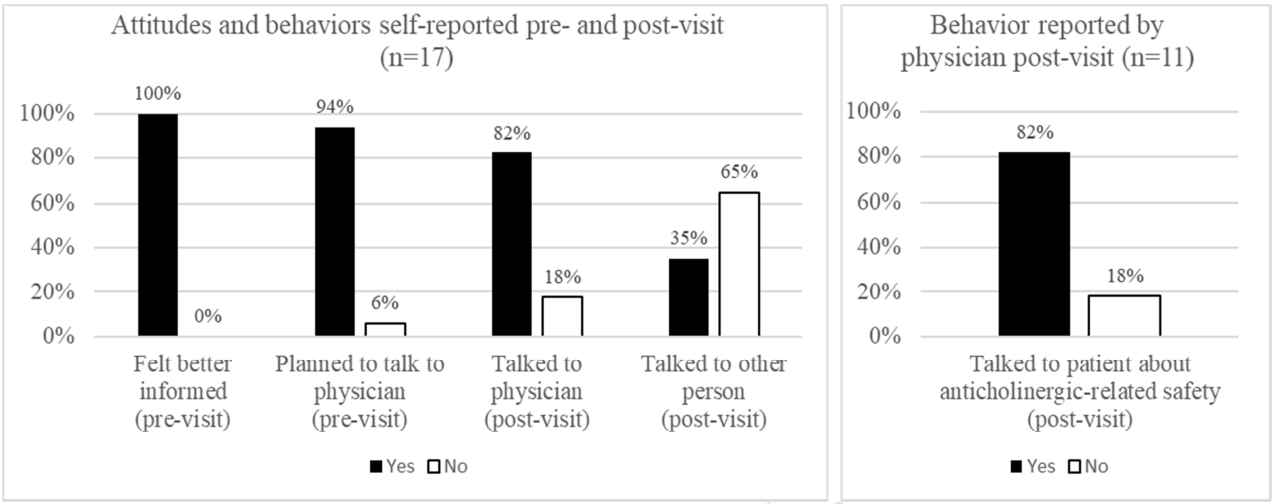
medication with a safer alternative, illustrated by one participant's comment, *"It became a situation where he's going to take me off the medication and replace it with another med."*

Table 2. Responses on positively- (#1-5) and negatively-worded (#6-10) SUS items (n=23).

	Response, N (%)					
SUS item	Strongly agree	Agree	Neither agree/ disagree	Disagree	Strongly disagree	**% usable**
1. Would use frequently	8 (35)	9 (39)	2 (9)	3 (13)	1 (4)	**74%**
2. Easy to use	12 (52)	10 (43)	0 (0)	1 (4)	0 (0)	**96%**
3. Parts well integrated	6 (26)	13 (57)	3 (13)	0 (0)	1 (4)	**83%**
4. Learning was quick	10 (43)	10 (43)	0 (0)	2 (9)	1 (4)	**87%**
5. Felt confident using	7 (30)	12 (52)	2 (9)	1 (4)	1 (4)	**83%**
6. Would need help to use	1 (4)	4 (17)	1 (4)	6 (26)	11 (48)	**74%**
7. Was confusing for me	0 (0)	1 (4)	1 (4)	8 (35)	13 (57)	**91%**
8. Too complex for me	2 (9)	1 (4)	2 (9)	5 (22)	13 (57)	**78%**
9. Was hard to use	0 (0)	0 (0)	1 (4)	8 (35)	14 (61)	**96%**
10. Would need to learn a lot to use	0 (0)	5 (22)	1 (4)	6 (26)	11 (48)	**74%**

SUS = System usability scale. Negatively-worded items are printed in italics. % usable indicates percent of respondents indicating agreement on positively-worded and disagreement on negatively-worded items.

Figure 4. Attitudes and self-reported behaviors (left) and physician confirmation* (right).



*A post-visit report could not be collected from the participant's physician in six cases.

DISCUSSION

In this study we performed usability and feasibility testing of Brain Buddy, a consumer-facing mHealth technology designed to reduce the risk of anticholinergic medications among older adults. mHealth technologies such as Brain Buddy can be powerful enablers of patients because they can provide just-in-time information access, efficient and effective communication channels, and continuous support.[49] mHealth can also democratize knowledge and reduce information asymmetry between patients and healthcare professionals, integrate large amounts of data from multiple sources, and present information in ways that support better decision making.[50] However, it is increasingly evident that mHealth technologies, especially for older adults, must be designed in a user-centered fashion and tested for usability, acceptability, and feasibility in real-world clinical settings.[10,51] Moreover, national studies show enduring digital divides among older adults, particularly gaps disadvantaging racial and ethnic minorities.[52,53] To avoid the phenomenon known as intervention-generated inequalities, produced by a focus on technologies and other interventions that help the 'haves' and hurt the 'have nots,'[54] it is

important to perform studies of usability, acceptability, and feasibility with demographically and socioeconomically diverse samples.

Usability

Brain Buddy was found to have acceptable usability for a demographically diverse sample of 23 older adults receiving primary care in a community health center. Self-reported usability scores were generally high, averaging between "Good" and "Excellent" and well above the normative average.[47] Like other recent studies with older adults reporting SUS scores for mHealth applications or medical devices,[34,41,55] we found some individuals reported low usability and made mistakes during use, especially on tasks requiring data entry. Very low scores, for example one outlying SUS score of 37.5 (> 2.5 SD of the mean), suggest even further redesign may not yield a product that everyone can use, due to disability, unease, or other factors.[56] Design changes can reduce certain errors, for example, by increasing the distance between buttons to minimize accidental button presses, whereas other mistakes are inevitable and the design goals should be to increase error recovery.[57] Examples of error recovery in the Brain Buddy are the ability to quickly edit accidentally selected medications and prominent back-navigation buttons. It is also possible that the design of Brain Buddy was reasonably usable, but that participants found medication-related tasks difficult due to pre-existing medication knowledge gaps; for example, a recent study reported 30% of their sample (mean age = 53) had difficulty naming at least one of their medications.[58] Future design could supplement written medication names with photos, to capitalize on individuals' knowledge of their medications' color, shape, and size.[59] Another strategy to circumvent medication knowledge gaps, as well as reduce burden and errors related to data entry, is using automation or passive sensing (the collection of data through sensors with no or minimal effort on the part of the individual).[60]

Although overall usability was acceptable, participants self-reported lower scores on learnability items (needing to learn, needing assistance), not surprising given participants were using Brain Buddy for the first time and some had never used a smartphone. We also observed that to perform more difficult tasks, up to 61% of participants needed encouragement, further instructions, and in a few cases demonstration by research staff. Learnability issues can be addressed with initial training, either in-person or via in-app tutorials, as well as clear instructions and help functionality.[61] Another possibility is designing the app for use by a proxy or with assistance, for example a family member who can provide encouragement, verbal instructions, or demonstrate use. The concept of designing medication aids for proxy or joint use has been explored among caregivers of juvenile patients,[62] but should be further studied with products for older adults.

Feasibility

All participants who provided feasibility data reported feeling better informed after using Brain Buddy and nearly all planned to speak to a physician about anticholinergic related risks. Additionally, 82% did indeed speak to their physician about anticholinergics and although we did not measure actual changes in medications, some reported self-initiating alternative therapies with their physician. This study was designed to initiate and measure patients' conversations with a physician, based on prior work on older adults' deference to physicians regarding both prescription and nonprescription medications.[33,63] While our findings support Brain Buddy's efficacy in initiating conversations, these findings should be treated with caution because of the small sample size, lack of control group, and no measure of actual changes in prescriptions and medication use.

It remains to be seen whether informing and activating older adults effectively changes prescribing behavior, compared to prescriber-oriented interventions. However, first, we believe consumer-oriented interventions can complement rather than replace interventions targeting physicians, pharmacists, and other clinicians. In a recent Cochrane review of interventions to reduce inappropriate use of medications in older adults, 11 of 12 (92%) controlled studies targeted clinicians;[64] this suggests unexplored opportunities to introduce consumer-oriented medication safety interventions.[31] Further work should examine the best way to combine consumer- and clinician-facing interventions for medication safety. Second, if effective, interventions using direct-to-consumer mHealth offer an inexpensive and scalable solution. We note prior attempts to influence anticholinergic medication use through physician-oriented interventions such as computerized provider order entry alerts or involving geriatricians have been unsuccessful because physicians disregarded alerts or were effective but difficult to scale.[26,65] Third, patients do indeed influence prescriber behavior. A series of studies published in the *British Medical Journal* demonstrated a considerable effect of patient requests and perceived patient preferences on prescribing activity.[66-70] Fourth, activating patients to enter into shared decision making is an accepted, evidence-based strategy underpinning new paradigms of healthcare delivery.[71,72] Therefore, rather than ask whether to target patients, a more relevant question is how to best achieve safer medication prescribing by leveraging patient involvement.

Study strengths and limitations

This study was performed on a technology designed and evaluated for usability at the outset, following standard user-centered design and testing methods. We recruited older adults from a real-world primary care setting and targeted individuals known to be prescribed anticholinergic medications. We performed summative usability of the fully interactive,

professionally developed application in the field, with older adult users of anticholinergic medications. Our sample size of 23 was large compared to typical usability studies.[43,44] We collected both self-report and observed performance-based usability data, important given the imperfect correlations between the two.[73] In addition, for 17 participants, we collected data on their self-reported attitudes and behavior, independently confirmed by physician reports. Such data are critical for technologies relying on behavior change.[74] The study was performed with patients differing in race, sex, and education, though predominantly non-White, less educated, and earning an annual household income < $25,000. Study limitations included testing with patients from a single health system who had no cognitive or visual impairment. We did not measure or recruit for diversity on literacy or health literacy, knowledge about medications, baseline patient activation, or other factors that may influence Brain Buddy usability and feasibility. In this study we did not measure comprehension of the educational videos, although these had been pre-tested with community stakeholders. Brain Buddy use occurred in the presence of a researcher and home use was not observed. As discussed above, we did not measure actual medication prescription, dispensing, or use behavior. The study did not have a control group, was cross-sectional, and had too small a sample size to draw conclusions about efficacy. Although our team included clinicians, we did not involve frontline clinicians in Brain Buddy design or testing.

Conclusion

In addition to addressing the above limitations, future work should examine how Brain Buddy and similar mHealth interventions can be used for other cases of medication safety or for nonpharmacological treatment. Additional work remains to integrate Brain Buddy and similar products into clinical workflow and technologies. Studies should test the costs, safety, and

efficacy (on prescribing, anticholinergic exposure, and cognition) of Brain Buddy alone and combined with other patient- and clinician-oriented medication safety interventions. Other work could examine paper-based versions of Brain Buddy or embed Brain Buddy in settings such as retail pharmacies. Furthermore, we recommend studies on strategies to ensure informing and activating patients result in safe medication changes over time and across contexts of care. This includes considerations for initiating and structuring patient-clinician communication about medication safety. For the time being, our findings support performing user-centered design and testing of mHealth and other digital health interventions, towards achieving older adult medication safety in a scalable and cost-effective manner.

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Conflict of interest statement

We declare no conflicts of interest.

References

1. Dentzer S. Rx for the 'blockbuster drug' of patient engagement. *Health Affairs*. 2013;32:202.
2. Carman KL, Dardess P, Maurer M, Sofaer S, Adams K, Bechtel C, et al. Patient and family engagement: A framework for understanding the elements and developing interventions and policies. *Health Affairs*. 2013;32:223-31.
3. Agoritsas T, Heen AF, Brandt L, Alonso-Coello P, Kristiansen A, Akl EA, et al. Decision aids that really promote shared decision making: the pace quickens. *BMJ*. 2015;350:g7624.
4. Davis S, Roudsari A, Raworth R, Courtney KL, MacKay L. Shared decision-making using personal health record technology: a scoping review at the crossroads. *Journal of the American Medical Informatics Association*. 2017;24:857-66.
5. Hamine S, Gerth-Guyette E, Faulx D, Green BB, Ginsburg AS. Impact of mHealth chronic disease management on treatment adherence and patient outcomes: a systematic review. *Journal of Medical Internet Research*. 2015;17:https://www.jmir.org/2015/2/e52/.
6. Santo K, Richtering SS, Chalmers J, Thiagalingam A, Chow CK, Redfern J. Mobile phone apps to improve medication adherence: A systematic stepwise process to identify high-quality apps. *JMIR Mhealth Uhealth*. 2016;4:https://mhealth.jmir.org/2016/4/e132/.
7. Finkelstein J, Knight A, Marinopoulos S, Gibbons MC, Berger Z, Aboumatar H, et al. Enabling patient-centered care through health information technology. Evidence Report/Technology Assessment No. 206. AHRQ Publication No. 12-E005-EF. Rockville, MD: Agency 2012 June.
8. Morawski K, Ghazinouri R, Krumme A, Lauffenburger JC, Lu Z, Durfee E, et al. Association of a Smartphone Application With Medication Adherence and Blood Pressure Control: The MedISAFE-BP Randomized Clinical Trial. *JAMA internal medicine*. 2018;178:802-9.
9. Ahmed I, Ahmad NS, Ali S, George A, Saleem Danish H, Uppal E, et al. Medication adherence apps: Review and content analysis. *JMIR Mhealth Uhealth*. 2018;6:https://mhealth.jmir.org/2018/3/e62/.
10. Goldberg L, Lide B, Lowry S, Massett HA, O'Connel T, Preece J, et al. Usability and accessibility in consumer health informatics: Current trends and future challenges. *Am J Prev Med*. 2011;40:5187-97.
11. Gray SL, Anderson ML, Dublin S, Hanlon JT, Hubbard R, Walker R, et al. Cumulative use of strong anticholinergics and incident dementia: a prospective cohort study. *JAMA internal medicine*. 2015;175:401-7.
12. Richardson K, Fox C, Maidment I, Steel N, Loke YK, Arthur A, et al. Anticholinergic drugs and risk of dementia: case-control study. *BMJ*. 2018;361:k1315.
13. Campbell NL, Lane KA, Gao S, Boustani MA, Unverzagt F. Anticholinergics influence transition from normal cognition to mild cognitive impairment in older adults in primary care. *Pharmacotherapy: The Journal of Human Pharmacology and Drug Therapy*. 2018.
14. Risacher SL, McDonald BC, Tallman EF, West JD, Farlow MR, Unverzagt FW, et al. Association between anticholinergic medication use and cognition, brain metabolism, and brain atrophy in cognitively normal older adults. *JAMA neurology*. 2016.
15. American Geriatrics Society Beers Criteria Update Expert P. American Geriatrics Society updated Beers Criteria for potentially inappropriate medication use in older adults. *J Am Geriatr Soc*. 2012;60:616-31.

16. Maust DT, Kim HM, Chiang C, Kales HC. Association of the Centers for Medicare & Medicaid Services' National Partnership to Improve Dementia Care With the Use of Antipsychotics and Other Psychotropics in Long-term Care in the United States From 2009 to 2014. *JAMA Internal Medicine*. 2018;178:640-7.
17. Institute of Medicine. Cognitive aging: Progress in understanding and opportunities for action. Washington, DC: National Academies Press; 2015.
18. Fox C, Richardson K, Maidment ID, Savva GM, Matthews FE, Smithard D, et al. Anticholinergic medication use and cognitive impairment in the older population: the medical research council cognitive function and ageing study. *J Am Geriatr Soc*. 2011;59:1477-83.
19. Campbell NL, Boustani M, Limbil T, Ott C, Fox C, Maidment I, et al. The cognitive impact of anticholinergics: a clinical review. *Clinical Interventions in Aging*. 2009;4:225-33.
20. McNeely SS, Bhattacharya R, Aparasu RR. Prevalence of anticholinergic use among older home health patients. *Journal of Clinical Nursing*. 2013;22:285-8.
21. Niznik J, Zhao X, Jiang T, Hanlon JT, Aspinall SL, Thorpe J, et al. Anticholinergic Prescribing in Medicare Part D Beneficiaries Residing in Nursing Homes: Results from a Retrospective Cross-Sectional Analysis of Medicare Data. *Drugs & aging*. 2017;34:925-39.
22. Kemper RF, Steiner V, Hicks B, Pierce L, Iwuagwu C. Anticholinergic medications: use among older adults with memory problems. *Journal of gerontological nursing*. 2007;33:21-31.
23. Thorpe JM, Thorpe CT, Kennelty KA, Gellad WF, Schulz R. The impact of family caregivers on potentially inappropriate medication use in noninstitutionalized older adults with dementia. *The American journal of geriatric pharmacotherapy*. 2012;10:230-41.
24. Albert SM, Roth T, Toscani M, Vitiello MV, Zee P. Sleep health and appropriate use of OTC sleep aids in older adults—Recommendations of a Gerontological Society of America workgroup. *The Gerontologist*. 2017;57:163-70.
25. Stone JA, Lester CA, Aboneh EA, Phelan CH, Welch LL, Chui MA. A preliminary examination of over-the-counter medication misuse rates in older adults. *Research in Social and Administrative Pharmacy*. 2017;13:187-92.
26. Boustani MA, Sachs GA, Alder CA, Munger S, Schubert CC, Guerriero Austrom M, et al. Implementing innovative models of dementia care: The Healthy Aging Brain Center. *Aging & mental health*. 2011;15:13-22.
27. Agostini JV, Zhang Y, Inouye SK. Use of a computer□based reminder to improve sedative–hypnotic prescribing in older hospitalized patients. *Journal of the American Geriatrics Society*. 2007;55:43-8.
28. Castelino RL, Hilmer SN, Bajorek BV, Nishtala P, Chen TF. Drug Burden Index and potentially inappropriate medications in community-dwelling older people: the impact of Home Medicines Review. *Drugs & aging*. 2010;27:135-48.
29. Efjestad AS, Molden E, Oksengard AR. Pharmacist-initiated management of antagonistic interactions between anticholinergic drugs and acetyl cholinesterase inhibitors in individuals with dementia. *J Am Geriatr Soc*. 2013;61:1624-5.
30. Kersten H, Molden E, Tolo IK, Skovlund E, Engedal K, Wyller TB. Cognitive effects of reducing anticholinergic drug burden in a frail elderly population: a randomized controlled trial. *The journals of gerontology Series A, Biological sciences and medical sciences*. 2013;68:271-8.
31. Tannenbaum C, Martin P, Tamblyn R, Benedetti A, Ahmed S. Reduction of inappropriate benzodiazepine prescriptions among older adults through direct patient education: the EMPOWER cluster randomized trial. *JAMA internal medicine*. 2014;174:890-8.

32. Martin P, Tamblyn R, Benedetti A, Ahmed S, Tannenbaum C. Effect of a pharmacist-led educational intervention on inappropriate medication prescriptions in older adults: The d-prescribe randomized clinical trial. *JAMA*. 2018;320:1889-98.
33. Holden RJ, Srinivas P, Campbell NL, Clark DO, Bodke KS, Hong Y, et al. Understanding older adults' medication decision making and behavior: A study on over-the-counter (OTC) anticholinergic medications. *Research in Social and Administrative Pharmacy*. 2019;15:53-60.
34. Srinivas P, Cornet V, Holden RJ. Human factors analysis, design, and testing of Engage, a consumer health IT application for geriatric heart failure self-care. *International Journal of Human-Computer Interaction*. 2017;33:298-312.
35. Akatsu H, Miki H, Hosono N. Design principles based on cognitive aging. *International Conference on Human-Computer Interaction*. 2007:3-10.
36. Fisk AD, Rogers WA, Charness N, Czaja SJ, Sharit J. Designing for Older Adults: Principles and Creative Human Factors Approaches. 2nd ed. Boca Raton, FL: CRC Press; 2009.
37. Bailey B. Age-Related Research-Based Usability Guidelines (usability.gov): usability.gov; 2005 [Available from: https://www.usability.gov/get-involved/blog/2005/11/age-related-guidelines.html.
38. Zikmund-Fisher BJ, Witteman HO, Dickson M, Fuhrel-Forbis A, Kahn VC, Exe NL, et al. Blocks, ovals, or people? Icon type affects risk perceptions and recall of pictographs. *Medical decision making*. 2014;34:443-53.
39. Kreuzmair C, Siegrist M, Keller C. Does iconicity in pictographs matter? The influence of iconicity and numeracy on information processing, decision making, and liking in an eye□tracking study. *Risk Analysis*. 2017;37:546-56.
40. Zikmund-Fisher BJ, Fagerlin A, Ubel PA. Risky feelings: why a 6% risk of cancer does not always feel like 6%. *Patient Education and Counseling*. 2010;81:S87-S93.
41. Cornet VP, Daley CN, Srinivas P, Holden RJ. User-Centered Evaluations with Older Adults: Testing the Usability of a Mobile Health System for Heart Failure Self-Management. *Proceedings of the Human Factors and Ergonomics Society Annual Meeting*. 2017;61:6-10.
42. Callahan CM, Unverzagt FW, Hui SL, Perkins AJ, Hendrie HC. Six-item screener to identify cognitive impairment among potential subjects for clinical research. *Medical Care*. 2002:771-81.
43. Macefield R. How to specify the participant group size for usability studies: a practitioner's guide. *Journal of Usability Studies*. 2009;5:34-45.
44. Schmettow M. Sample size in usability studies. *Communications of the ACM*. 2012;55:64-70.
45. Bangor A, Kortum PT, Miller JT. An empirical evaluation of the System Usability Scale. *International Journal of Human-Computer Interaction*. 2008;24:574-94.
46. Sauro J. Measuring Usability With The System Usability Scale (SUS) 2011 [Available from: http://www.measuringu.com/sus.php.
47. Bangor A, Kortum P, Miller J. Determining what individual SUS scores mean: Adding an adjective rating scale. *Journal of usability studies*. 2009;4:114-23.
48. Lewis J, Sauro J. The factor structure of the system usability scale, international conference. *Human Computer Interaction International*. 2009.
49. Wang J, Wang Y, Wei C, Yao N, Yuan A, Shan Y, et al. Smartphone interventions for long-term health management of chronic diseases: an integrative review. *Telemedicine and e-Health*. 2014;20:570-83.

50. Kim B, Lee J. Smart devices for older adults managing chronic disease: A scoping review. *JMIR MHealth UHealth*. 2017;5:https://mhealth.jmir.org/2017/5/e69/.
51. Valdez R, Holden R, Novak L, Veinot T. Transforming consumer health informatics through a patient work framework: Connecting patients to context. *J Am Med Inform Assoc*. 2014;ePub:1-7.
52. Mitchell UA, Chebli PG, Ruggiero L, Muramatsu N. The Digital Divide in Health-Related Technology Use: The Significance of Race/Ethnicity. *The Gerontologist*. 2018.
53. Smith A. Older adults and technology use: Pew Research Center [Internet & American Life Project]; 2014.
54. Veinot TC, Mitchell H, Ancker JS. Good intentions are not enough: how informatics interventions can worsen inequality. *Journal of the American Medical Informatics Association*. 2018;25:1080-8.
55. Gao M, Kortum P. Measuring the Usability of Home Healthcare Devices Using Retrospective Measures. *Proceedings of the Human Factors and Ergonomics Society Annual Meeting*. 2017;61:1281-5.
56. Mitzner TL, Savla J, Boot WR, Sharit J, Charness N, Czaja SJ, et al. Technology adoption by older adults: Findings from the PRISM trial. *The Gerontologist*. 2019;59:34-44.
57. Holden RJ, Voida S, Savoy A, Jones JF, Kulanthaivel A. Human Factors Engineering and Human–Computer Interaction: Supporting User Performance and Experience. In: Finnell JT, Dixon BE, editors. Clinical Informatics Study Guide. New York: Springer; 2015. p. 287-307.
58. Fredericksen R, Gibbons L, Brown S, Edwards T, Yang F, Fitzsimmons E, et al. Medication understanding among patients living with multiple chronic conditions: Implications for patient-reported measures of adherence. *Research in Social and Administrative Pharmacy*. 2018;14:540-4.
59. Lenahan JL, McCarthy DM, Davis TC, Curtis LM, Serper M, Wolf MS. A drug by any other name: patients' ability to identify medication regimens and its association with adherence and health outcomes. *Journal of health communication*. 2013;18:31-9.
60. Cornet VP, Holden RJ. Systematic review of smartphone-based passive sensing for health and wellbeing. *Journal of biomedical informatics*. 2018;77:120-32.
61. Stiles-Shields C, Montague E, Lattie EG, Schueller SM, Kwasny MJ, Mohr DC. Exploring user learnability and learning performance in an app for depression: usability study. *JMIR human factors*. 2017;4.
62. Brinkman WB, Lipstein EA, Taylor J, Schoettker PJ, Naylor K, Jones K, et al. Design and implementation of a decision aid for juvenile idiopathic arthritis medication choices. *Pediatric Rheumatology*. 2017;15:48.
63. Serper M, McCarthy DM, Patzer RE, King JP, Bailey SC, Smith SG, et al. What patients think doctors know: Beliefs about provider knowledge as barriers to safe medication use. *Patient education and counseling*. 2013;93:306-11.
64. Cooper JA, Cadogan CA, Patterson SM, Kerse N, Bradley MC, Ryan C, et al. Interventions to improve the appropriate use of polypharmacy in older people: a Cochrane systematic review. *BMJ open*. 2015;5:e009235.
65. Boustani MA, Campbell NL, Khan BA, Abernathy G, Zawahiri M, Campbell T, et al. Enhancing care for hospitalized older adults with cognitive impairment: a randomized controlled trial. *Journal of general internal medicine*. 2012;27:561-7.

66. Britten N, Ukoumunne O. The influence of patients' hopes of receiving a prescription on doctors' perceptions and the decision to prescribe: a questionnaire survey. *Bmj*. 1997;315:1506-10.
67. Jones MI, Greenfield SM, Bradley CP. Prescribing new drugs: qualitative study of influences on consultants and general practitioners. *Bmj*. 2001;323:378.
68. Little P, Dorward M, Warner G, Stephens K, Senior J, Moore M. Importance of patient pressure and perceived pressure and perceived medical need for investigations, referral, and prescribing in primary care: nested observational study. *Bmj*. 2004;328:444.
69. Little P, Dorward M, Warner G, Moore M, Stephens K, Senior J, et al. Randomised controlled trial of effect of leaflets to empower patients in consultations in primary care. *bmj*. 2004;328:441.
70. Macfarlane J, Holmes W, Macfarlane R, Britten N. Influence of patients' expectations on antibiotic management of acute lower respiratory tract illness in general practice: questionnaire study. *Bmj*. 1997;315:1211-4.
71. Shay LA, Lafata JE. Where is the evidence? A systematic review of shared decision making and patient outcomes. *Medical Decision Making*. 2015;35:114-31.
72. Hibbard JH. Patient activation and the use of information to support informed health decisions. *Patient education and counseling*. 2017;100:5-7.
73. Gao M, Kortum P. The relationship between subjective and objective usability metrics for home healthcare devices. *Proceedings of the Human Factors and Ergonomics Society Annual Meeting*. 2015;59:1001-5.
74. Pavel M, Jimison HB, Korhonen I, Gordon CM, Saranummi N. Behavioral informatics and computational modeling in support of proactive health management and care. *IEEE Transactions on Biomedical Engineering*. 2015;62:2763-75.

Appendix A. Prescription anticholinergics used in eligibility screening.

1. Cyclobenzaprine

2. Oxybutynin

3. Olanzapine

4. Amitriptyline

5. Hydroxyzine

6. Paroxetine

7. Quetiapine

8. Meclizine

9. Nortriptyline

10. Dicyclomine

11. Tolterodine

12. Doxepin

13. Methocarbamol