



Potential normalization of an asthma mHealth intervention in community pharmacies: Applying a theory-based framework

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ABSTRACT

Background: Effective mobile health (mHealth) interventions have been developed to support patients with their medication use, however to date few are widely used in pharmacy practice. Normalization of an intervention is essential to have a population impact, which is defined as ‘the process of getting a new intervention into routine practice’.

Objective: The aim of this study was to assess the normalization potential of a complex mHealth intervention for adolescents with asthma (ADolescent Adherence Patient Tool; ADAPT) in community pharmacy practice.

Methods: The Normalization Process Theory (NPT), a sociological action theory, was retrospectively applied to study the normalization potential of ADAPT. NPT explains factors that promote or hinder implementation, embedding, and integration of new interventions in clinical practice. Evaluation data (structured interviews and questionnaires) of 23 pharmacists who used the ADAPT intervention were used for this study.

Results: Pharmacists understood the purpose of the ADAPT intervention and were prepared to undertake the necessary work of implementation. However changes at different levels are needed to support full normalization, such as changes in the intervention itself and changes in the pharmacist's work flow. The potential for normalization could also be enhanced by the use of product champions and appropriate reimbursement guidelines, to ensure uptake of the intervention by other pharmacists. Support from professional bodies for the use of mHealth could also promote normalization.

Conclusions: Normalization of mHealth is a complex continuous process. The ADAPT intervention has the potential to be normalized in community pharmacy practice, but full normalization would require changes in both daily pharmacy practice and reimbursement models.

Introduction

Suboptimal asthma control is common, i.e., around 50% of patients have uncontrolled asthma, mostly caused by medication non-adherence. Patients with uncontrolled asthma are at increased risk of exacerbations, which can result in hospitalizations or even deaths. Furthermore, decreased quality of life has been described.^{1,2} These consequences contribute to increased healthcare costs for society.

Non-adherence rates are especially high during adolescence.³ Mobile health (mHealth) interventions have the potential to support patients with their medication use, and can be in particular interesting for

adolescents.^{4,5} Medication intake behaviour is complex as it is affected by multiple unintentional (practical) and intentional (perceptual) barriers.⁶ Therefore, interventions with multiple components are more effective in improving medication adherence than those aimed at only one aspect of non-adherent behaviour.^{7,8} Several mHealth interventions with multiple components have been developed and use of these interventions resulted in increased adherence rates, improved self-management, or improved health status.^{9–12} However, hardly any of them are currently implemented in clinical practice.

Complex interventions may be hard to implement in clinical practice, as they often require change at multiple levels involving different

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Table 1
Terminology and definitions used in the Normalization Process Theory (NPT).

Term	Definition
Normalization	To become part of routine practice, i.e., to take it for granted
Embedding	The process through which a practice (e.g., use of a new intervention) become routinely incorporated in everyday work of individuals and groups
Implementation	The social organization of bringing a practice (e.g., use of a new intervention) into action, thus actually using the intervention
Integration	The process by which a practice (e.g., use of a new intervention) is reproduced and sustained among social matrices of an organization or institution

Table 2
The four constructs of the Normalization Process Theory (NPT) with the four corresponding components.

Construct	Components	Explanation
Coherence <i>Sense-making</i>	Internalization	Understanding the value, benefits, and importance
	Individual specification	Understanding specific individual tasks and responsibilities
	Differentiation	Understanding the distinctiveness
	Communal specification	Working together with others to build a shared understanding of the aim, objective, and expected benefits
Cognitive participation <i>Effort</i>	Initiation	Key participants drive implementation forward
	Enrolment	Organizing or reorganizing of participants (and others) to collectively contribute
	Legitimation	Ensuring that other participants believe it is right for them to be involved, and can make a valid contribution
	Activation	Defining the actions and procedures needed to sustain using mHealth and stay involved
Collective action <i>Commitment</i>	Interactional workability	Impact on interactions, particularly the interactions between healthcare professionals and patients (consultations)
	Relational integration	Impact on relations between groups of professionals
	Skill set workability	Fit between new intervention and existing skill sets
	Contextual integration	Fit with overall organizational context; goals, morale, leadership and resources
Reflexive monitoring <i>Appraisal</i>	Systematization	Determining how effective and useful it is for participants and for others
	Communal appraisal	Working together (in formal collaboratives, or in informal groups) to evaluate the worth
	Individual appraisal	Working experientially as individuals to appraise its effects on them and the contexts in which they are set
	Reconfiguration	Attempting to redefine procedures or modify the intervention itself

stakeholders, e.g., the patient, the healthcare professional, the healthcare organization, and the wider environment such as the national healthcare system.^{13–17} These contextual factors are dynamic and can change over time. It has been suggested that the fit between an intervention and its context determines the success of the implementation.¹³

Implementation science focuses on strategies to promote the uptake of interventions into routine practice. The Normalization Process Theory (NPT), a sociological action theory, focusses on the *work* required to implement new interventions in clinical practice. Normalization is defined as ‘to become part of routine practice’, and it covers different stages: implementation, embedding, and integration (Table 1).^{18,19} NPT was developed to address factors that promote or hinder implementation, embedding, and integration of new practices.¹⁸ It can be used to describe how complex healthcare interventions can become normalized.

Prior research showed that the ADolescent Adherence Patient Tool (ADAPT), a pharmacy based interactive mHealth intervention, improved medication adherence in adolescents with asthma having poor adherence rates.²⁰ However, the population impact of an intervention depends on both the effect size and the extent to which the intervention reaches the target population.²¹ Thus the actual impact of an intervention is likely to be enhanced by integration into routine clinical practice.^{14,19} Most previously developed mHealth interventions were local or isolated initiatives. Hardly any intervention is widely implemented and not much attention has been paid to a sustained normalization plan.^{11,12,22} Therefore, the aim was to study the normalization potential of a mHealth intervention for adolescents with asthma in the community pharmacy, using the ADolescent Adherence Patient Tool (ADAPT) as an example.

Methods

Study design, setting, and participants

The NPT is retrospectively applied, per construct and per component, to the ADAPT intervention.^{20,23} Evaluation data from the ADAPT study (which were previously collected) were used for this research.²⁴

The ADAPT study was a cluster randomised controlled trial to evaluate the effectiveness of the newly developed ADAPT intervention in Dutch community pharmacies. This study was approved by the Medical Review Ethics Committee of the University Medical Centre Utrecht (NL50997.041.14) and by the Institutional Review Board of the Utrecht Pharmacy Practice network for Education and Research (UPPER). In total, 66 pharmacists (independent pharmacies, of which some were part of pharmacy chains) individually decided to participate in the ADAPT study. Of these, 23 had access to the ADAPT intervention. At the end of the ADAPT study, a research assistant conducted structured interviews with those pharmacists to evaluate their experiences with the intervention. These structured interviews (i.e., questionnaires) contained open-ended questions on their experiences with the ADAPT intervention and their perceptions on implementation and integration in clinical practice. The pharmacists also completed a brief questionnaire where they used a 5-point Likert scale (totally agree to totally disagree) for statements related to their experiences and opinions about the ADAPT intervention.²⁴ The NPT was retrospectively applied to the evaluation data and the NPT Toolkit, consisting of 16 questions,²⁵ was used to evaluate the implementation, embedding, and integration of ADAPT in daily pharmacy practice.

Normalization Process Theory (NPT)

NPT is a sociological action theory, proposing first that complex interventions become routinely embedded and integrated in contexts as the result of people working, individually and collectively, to implement them. Action is regarded as more important than people's attitudes or intentions when implementing an intervention in healthcare. Second, the work of implementation is operationalized through four constructs of social action (Table 2); (1) coherence: *does it make sense?*, (2) cognitive participation: *do I want to take part?*, (3) collective action: *what is the impact on work?*, and (4) reflexive monitoring: *is it worth it?* These four constructs represent different stages and different kinds of work that people do as they work around a set of new practices, such as the use of a new intervention. Lastly, NPT proposes that the integration of a complex intervention requires continuous investment by people

that carry forward in space and time. This means that continuous investing in sense-making, effort, commitment, and appraisal are necessary for the normalization of a complex intervention.

ADolescent Adherence Patient Tool (ADAPT)

The ADAPT intervention consisted of a smartphone application (app) for patients (iOS or Android), which was connected to a desktop management system of the patient's own community pharmacist. In the Netherlands, patients are usually registered in one single pharmacy and generally collect all their prescription medication in that specific pharmacy. The ADAPT intervention was an interactive mHealth intervention with several components to support different aspects of medication adherence and self-management: a weekly questionnaire to monitor symptoms, a medication reminder, short educational and motivational movies, a peer chat, and the opportunity to contact the pharmacist. During the ADAPT study, pharmacists and patients voluntarily participated and they had free access to the intervention. During the study, patient information was encrypted, using a code consisting of a pharmacy and patient number, to ensure privacy. All (personal) app data were encrypted using 128-bits Advanced Encryption Standard (AES) and were securely saved using Hypertext Transfer Protocol with a Secure Sockets Layer (HTTPS with SSL certificate). More details on the ADAPT intervention and study design have been described elsewhere.^{20,23}

Pharmacists were asked to support patients with their medication use by contacting them via chat messages, sending additional movies, or adjusting the frequency of the symptom monitor, if needed. Pharmacists received e-mail notifications when patients sent a chat message or when the weekly symptom monitor indicated poor symptom control. All use of the app was recorded automatically. The ADAPT intervention was evaluated in a six months cluster randomised controlled trial with 234 patients, and improved adherence in adolescents with asthma demonstrating poor adherence rates.²⁰

Data analysis

The structured interviews with pharmacists were audiotaped and the recordings were transcribed verbatim. Summaries of responses per question were made, and a combination of analytical techniques (searching and finding answers to the questions) and tactics (connecting similar answers) were used to obtain a comprehensive data overview. NPT was mapped onto this data, i.e., retrospective thought experiment. The results were discussed with experts involved with the development of the NPT, resulting in several hypothesis results. Questionnaire data were divided in three groups per statement: agree (fully agree and agree), neutral, and disagree (disagree and totally disagree). Descriptive statistics were calculated using IBM SPSS Statistics for Windows, version 24.0.

Results

The pharmacist descriptives are shown in Table 3, and the results of the brief questionnaire are shown in Table 4. The results of the application of NPT to ADAPT are described below and summarized in Fig. 1.

Coherence

The concept of coherence refers to the extent to which users can make sense of the intervention. There are four subsidiary constructs: differentiation (the extent to which the intervention can be differentiated from similar interventions), communal specification (shared understanding of the intended benefits), individual specification (individual understanding of the intended benefits and the work required to realise these benefits), and internalization (understanding the value, benefits, and importance of the intervention).²⁵

Table 3

Characteristics of the study population (N = 23).

Pharmacist characteristics	Mean (sd)
Female gender, % (n)	73.9 (17)
Age (years)	35.1 (9.0)
Working experience (years)	9.6 (8.1)
Number of patients who participated per pharmacy	3.3 (1.8)
Pharmacy characteristics	
Pharmacists (FTE)	1.7 (0.6)
Pharmacy technicians (FTE)	6.4 (3.2)
Located in urban environment, % (n)	65.2 (15)
Located in health centre, % (n)	65.2 (15)

FTE = Full Time Equivalent; sd = standard deviation.

Differentiation

Pharmacists were easily able to differentiate ADAPT from alternative methods to improve adherence to asthma medication, as, for most of them, this was their first experience with mHealth in the pharmacy. The ADAPT intervention consisted of a unique combination of interactive components to improve adherence. Pharmacists were aware that the desktop management system enabled the use of multiple components, such as the pharmacist chat, that facilitated contact between patients and pharmacist. These electronic consults (e-consults) were new for patients and pharmacists (Table 4).

Communal specification

Pharmacists who participated in the ADAPT study were aware of the problem of sub-optimal adherence to asthma medication in adolescents, agreed that this was an important problem, and understood that ADAPT aimed to improve adherence. Moreover, almost all pharmacists (22/23) thought that the pharmacy is the right place for mHealth interventions, like ADAPT, which indicates that they collectively perceive medication adherence as their responsibility. At the same time it was not clear whether and how pharmacists worked within their pharmacies with others to come to a shared understanding of using ADAPT in their specific context.

"The pharmacy is the right place for mHealth interventions like ADAPT, because medication adherence and medication counselling belong to the core business of pharmacists." Male pharmacist, age 50 years.

Individual specification

To ensure individual specification, a half-day training about 'asthma and medication use by adolescents' was organized at the start of the ADAPT study, which was rated as useful by two thirds of the pharmacists (Table 4). In addition, pharmacists received instructions in the pharmacy how to use the ADAPT intervention and an intervention guide was designed to explain the (use of the) intervention. Most pharmacists (18/23) stated that they understood their specific tasks and responsibilities, such as using the intervention when receiving e-mail notifications. Some pharmacists (7/23) reported requiring additional information to implement the intervention in clinical practice, and suggested an electronic support manual integrated into the intervention.

"The e-mail notifications were easy to deal with and they could easily be found in the system." Female pharmacists, age 29 years

Internalization

The aim of the ADAPT intervention was to increase adherence among adolescents with asthma. Pharmacists voluntarily participated in the ADAPT study, and were thereby self-selecting and not surprisingly, already convinced of the importance of improving adherence. However, only 7 out of 23 pharmacists were familiar with electronic health (eHealth) interventions in the pharmacy, including mHealth.

Table 4

Overview of the pharmacists' opinion (N = 23) about the ADollescent Adherence Patient Tool (ADAPT).

	Agree % (n)	Neutral % (n)	Disagree % (n)
Before start of the study			
I am familiar with electronic health in pharmacy	30.4 (7)	13.0 (3)	56.5 (13)
The training was useful ^a	66.7 (12)	33.3 (6)	N/A
Use of the ADAPT intervention			
I used the intervention during the whole study period	73.9 (17)	N/A	26.1 (6)
Use of intervention was clear	78.3 (18)	8.7 (2)	13.0 (3)
Use of intervention was not time consuming	91.3 (21)	4.3 (1)	4.3 (1)
Evaluation of the intervention			
I'm satisfied with the intervention	95.6 (22)	N/A	4.4 (1)
Use of the intervention resulted in better insight in symptoms and medication use of patients	56.5 (13)	30.4 (7)	13.0 (3)
Use of the intervention resulted in improved medication use of patients	47.8 (11)	34.8 (8)	17.4 (4)
Use of the intervention facilitated contact between patients and pharmacists	73.9 (17)	21.7 (5)	4.3 (1)
Use of the intervention assisted the pharmacist with medication guidance of patients	82.6 (19)	13.0 (3)	4.3 (1)
Further implementation			
I require additional information to implement the intervention in clinical practice	30.4 (7)	26.1 (6)	43.5 (10)
Integration of the ADAPT desktop application in the pharmacy computer system will support implementation	100 (23)	N/A	N/A
I would like to use the intervention when reimbursed	91.3 (21)	N/A	8.7 (2)
The pharmacy is the right place for mHealth	95.6 (22)	N/A	4.3 (1)

^a 18 pharmacists participated in the training.

Thus, future implementation strategies should include an emphasis on the importance of adherence and the benefits of the ADAPT intervention as a starting point to ensure sense-making among pharmacists as well as providing information about the potential benefits of mHealth.

Cognitive participation

The second stage of normalization is about commitment, i.e., “do I want to participate”, including the role of key participants, reorganization of tasks, and defining actions to stay involved. The four constructs which make up cognitive participation are initiation, enrolment, legitimization, and activation.²⁵

Initiation

Initiation refers to the extent to which key participants drive the work of implementation forward. In this case, pharmacists were expected to support patients by chat messages, sending additional movies, and adjusting the frequency of the symptom questionnaire if needed. In the current study, initiation was supported by the research team sending a monthly digital newsletter aiming to motivate and remind the participating pharmacists to be actively involved in use of the

intervention. Data showed that most pharmacists contacted patients through the pharmacist chat, and monitored patients' symptoms. However, not many additional movies were sent³⁰.

Enrolment

Enrolment refers to the extent to which participants have to (re-) organize themselves and others, in order to implement the intervention. Pharmacists need to change their daily routine in order to create time to use a new intervention. As the number of enrolled adolescents per pharmacy was relatively low, the total time devoted to the use of the ADAPT intervention remained limited (Table 4). This supported enrolment in the context of this research. However, with more widespread use of the intervention, the time required would be a significant barrier unless reimbursement systems were changed to reflect this additional work.²⁴ Twenty-one of the 23 participating pharmacists stated they would continue to use the ADAPT intervention in clinical practice only if their time would be reimbursed.

“Use of the ADAPT intervention costed very little time, approximately 5–10 minutes per week” Male pharmacist, age 40 years

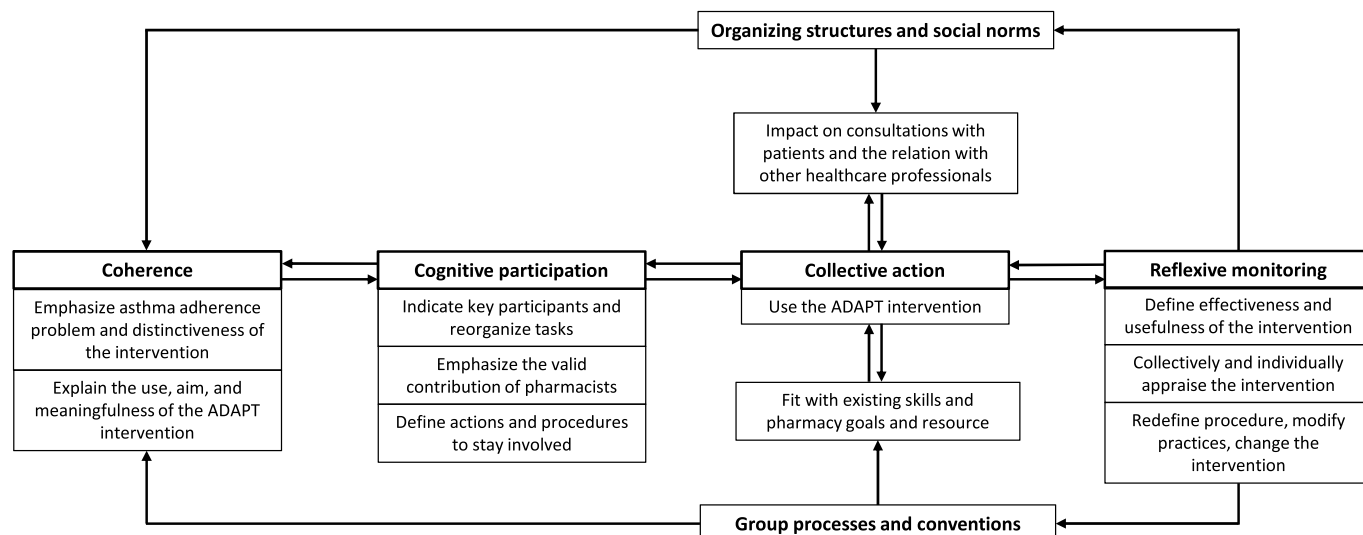


Fig. 1. The Normalization Process Theory (NPT) model applied to the ADollescent Adherence Patient Tool (ADAPT); an interactive asthma mHealth intervention in the pharmacy setting.

Legitimation

Legitimation refers to participants believing that promoting the implementation is a legitimate part of their role. Almost all pharmacists in this study thought that the pharmacy was the right place for mHealth interventions like ADAPT (Table 4). Moreover, around half of the pharmacists thought that they could eventually make a valid contribution, because the ADAPT intervention resulted in improved medication use (11/23) and the intervention improved their insights into patients' asthma symptoms and medication use (13/23).

Activation

Activation is about defining actions and procedures to remain involved with the intervention. In order to support pharmacists, an intervention guide was developed to explain (the use of) the intervention. Moreover, in the desktop application a decision tree was added to support proper use of the intervention, i.e., define the appropriate actions. Additionally, pharmacists received e-mail notifications when patients needed help and a monthly digital newsletter reminded pharmacists to stay involved. For most pharmacists, the use of the intervention was clear and they used the intervention for the whole study period (Table 4). Unfortunately no (quantitative) data was available on the use of the intervention guide, and the usefulness of the decision tree.

"The ADAPT intervention was easy to work with, it was very clear to me." Female pharmacist, age 29 years

Collective action

The next stage of the normalization process is collective action, which refers to the impact on work and workflows of getting the intervention routinely embedded in clinical practice. The four constructs of collective action are interactive workability, relational integration, skill set workability, and contextual integration. In the ADAPT study, most pharmacists (17/23) used the ADAPT intervention during the complete study period.

Interactional workability

Interactional workability refers to the extent of which the intervention improved interactions between pharmacists and adolescents. In total, 17 of the 23 pharmacists agreed that the intervention facilitated such contact. The e-consults were an addition to current consultations and they contributed to co-operative interactions, such as shared-decision making.²⁶

"I used the chat function quite often. The patient completed the questionnaire to monitor symptoms which was nice, and sometimes I needed to contact the patient based on the symptom score. The direct contact thought the chat was new, because normally I would call them afterwards." Male pharmacist, age 31 years

Relational integration

Relational integration refers to the impact of the intervention on accountability, responsibility, and trust between the users. The ADAPT intervention provided a role for pharmacists. As for most pharmacists (19/23) the intervention assisted with the medication guidance of patients.

Skill set workability

Skill set workability is the extent to which existing skills of professionals fit with a new intervention. The use of the ADAPT intervention was allocated to pharmacists as their responsibility is to ensure right medication use of patients. In two pharmacies, a pharmacy technician specialized in asthma care was appointed to use the ADAPT intervention (Table 3). Using mHealth in clinical practice is new. Therefore, it is important that healthcare providers develop the right skills to support

normalization. These skills can be acquired through trainings and workshops.²⁷ For most pharmacists the use of the ADAPT intervention was clear and most pharmacists thought the training was useful (Table 4).

"Clear instructions. I liked ADAPT." Female pharmacist, age 25 years

Contextual integration

Contextual integration refers to the fit with the overall organizational context. The ADAPT intervention contributed to integrated care and it delivered tools to pharmacists for medication counselling and for providing extra care, which does fit with the ongoing expanding role of pharmacists.²⁸ All pharmacists thought that an integration of the ADAPT stand-alone desktop application in the pharmacy computer system would support further implementation (Table 4).

Reflexive monitoring

The last stage of normalization is reflexive monitoring, which is the appraisal work that people do covering the effectiveness of the intervention and the redefinition of procedures. The four constructs which contribute to reflexive monitoring are systematization, communal appraisal, individual appraisal and reconfiguration.

Systematization

Systematization refers to the effectiveness and usefulness of an intervention. The ADAPT intervention was evaluated in a cluster randomised controlled trial, showing that the intervention effectively improved adherence in adolescents with asthma having poor adherence rates.²⁰ The pharmacist chat was the most effective component, which is in line with previous studies.^{29,30}

Communal and individual appraisal

Communal and individual appraisal refers to working together, or individually, to evaluate the worth of the intervention and to appraise its effects on them and on the contexts. Almost all pharmacists (95.6%; 22/23) were satisfied with the ADAPT intervention. They were in general positive about the effect of the intervention for patients and themselves (Table 4). For some pharmacists, the ADAPT intervention did not meet their expectations (43.5%; 10/23). Their reasons included a low number of participating patients per pharmacy, reluctance of patients, time constraints, and non-intuitiveness of the intervention.

"I really liked participating in the ADAPT study and the training at the start was also very useful." Female pharmacists, age 29 years

Reconfiguration

Reconfiguration is about attempts to redefine procedures, modify practices, and change the intervention itself. The ADAPT intervention was especially effective in improving medication adherence in those at greatest risk.²⁰ Therefore, it might be useful if pharmacists could select non-adherent patients and provide them access to the intervention, i.e., tailor the intervention. Additionally, an integration of the ADAPT intervention in the pharmacy computer system and reimbursement guidelines will support the normalization of the intervention (Table 4).

Discussion

This study describes all factors related to the normalization of a complex asthma mHealth intervention in the community pharmacy setting. The findings tentatively suggest that the ADAPT intervention has the potential to become normalized in clinical practice as long as there is adequate financial reimbursement for the additional work required by pharmacists and sufficient investment in training and motivating pharmacists to use it. These factors require change at the health service level, and lack of such change may inhibit the normalization of

mHealth in clinical practice.

The context of an intervention is important when trying to implement it in clinical practice.^{13,19} In the current study, a mHealth intervention for adolescents with asthma in the community pharmacy was used as an example. Thus, the normalization potential may differ for other contexts or patient groups. Moreover, it should be taken into account that trials, like the ADAPT study, are not best suited to evaluate the normalization potential of complex interventions in real life. Trials are closed systems with strict requirements for the population and the intervention use, while interventions should eventually be integrated in a dynamic real-world environment. More (or other) barriers may emerge when implementing a new intervention in the real-world environment. For example not all pharmacists will have a positive attitude towards the intervention, or be motivated to normalize the intervention. A product champion (initiation) is therefore important to support pharmacists in using the intervention. Ideally the intervention should be continuously evaluated during an implementation phase after the efficacy of the intervention has been shown.³¹

If the ADAPT mHealth intervention is normalized, it has the potential to support medication adherence of non-adherent patients,²⁰ and it can facilitate integration of care among different healthcare providers (including pharmacists, physicians, and nurses). For example the physician's role might be affected if the healthcare providing role of pharmacists increases.³² Further research should therefore focus on the inclusion of other healthcare practices. Ultimately mHealth might be added to multidisciplinary treatment guidelines to support normalization.

Different research fields focus on the implementation of new interventions in healthcare,^{13–17} and many models have been developed.^{16,33,34} For example, cognitive science suggests that increased knowledge increases implementation, behavioural science suggests that implementation is influenced by feedback and incentives, marketing science suggests a clear and attractive intervention, social science suggests a change in social norms, and organizational science suggests a change on system levels.¹⁵ In this study a sociological model was used, because sociology (i.e., the study of human social relationships, institutions, and society) is important when focussing on the implementation of new interventions in a complex and dynamic everyday healthcare setting.³⁵ It is now time to start implementing mHealth,³⁶ and the Normalization Process Theory is an action theory proposing that the implementation of an intervention in healthcare is the product of action, not necessarily people's attitudes or intentions. NPT also highlights all relevant aspects related to normalization (implementation, embedding, and integration), which makes it a complementary theory.

Limitations

In the current study, the normalization potential of a mHealth intervention was studied by retrospectively applying NPT and this approach has some limitations. Data were collected using a structured questionnaire that was not informed by NPT, and therefore did not address all the relevant elements of NPT. For other implementation studies, it is recommended to use the NPT at the start of the study when developing the questionnaires, to ensure sufficient arguments to confirm or reject a hypothesis. Secondly, the pharmacists in the ADAPT study voluntarily participated, and were probably positively biased towards the intervention, and therefore more likely to demonstrate cognitive participation. Despite these limitations, this study highlights aspects which are important for normalization and might need extra attention when trying to get a new intervention in routine pharmacy practice. Further research should focus on how to get other pharmacists (with a neutral or negative attitude) involved in using mHealth. The first steps to do this are described in the current study; ensure sense-making and cognitive participation. Support from the pharmacist community (and upper management in pharmacy chains) to use

mHealth may also be important to attain greater implementation.

Conclusions

Normalization of a complex mHealth intervention, like ADAPT, is a complex process, which involves changes at different levels and requires continuous investment of pharmacists. The ADAPT intervention may have the potential to become normalized, as sense-making, effort, commitment, and appraisal were predominantly positive in this sample. However changes in pharmacy practice appear to be needed to integrate mHealth into daily routine. These changes apply to the intervention, work flow, and appointing a product champion. Moreover, reimbursement and the support of professional bodies are likely to promote implementation and normalization.

Conflicts of interest

The authors have no conflicts of interest to declare.

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References

- Engelkes M, Janssens H, de Jongste JC, Sturkenboom MCJM, Verhamme KMC. Medication adherence and the risk of severe asthma exacerbations: a systematic review. *Eur Respir J*. 2015;45:396–407. <https://doi.org/10.1183/09031936.00075614>.
- Jentzsch NS, Silva GCG, Mendes GMS, Brand PLP, Camargos P. Treatment adherence and level of control in moderate persistent asthma in children and adolescents treated with fluticasone and salmeterol. *J Pediatr*. 2019;95(1):69–75. <https://doi.org/10.1016/j.jped.2017.10.008>.
- McQuaid EL, Kopel SJ, Klein RB, Fritz GK. Medication adherence in pediatric asthma: reasoning, responsibility, and behavior. *J Pediatr Psychol*. 2003;28(5):323–333. <https://doi.org/10.1093/jpepsy/jsg022>; 2015.
- 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. *J Med Internet Res*. 2015;17(2):e52. <https://doi.org/10.2196/jmir.3951>.
- Whitehead L, Seaton P. The effectiveness of self-management mobile phone and tablet apps in long-term condition management: a systematic review. *J Med Internet Res*. 2016;18(5):e97. <https://doi.org/10.2196/jmir.4883>.
- Horne R. Compliance, adherence, and concordance: implications for asthma treatment. *Chest*. 2006;130(1 Suppl):65S–72S. https://doi.org/10.1378/chest.130.1_suppl.65S.
- Dean AJ, Walters J, Hall A. A systematic review of interventions to enhance medication adherence in children and adolescents with chronic illness. *Arch Dis Child*. 2010;95(9):717–723. <https://doi.org/10.1136/adc.2009.175125>.
- Nieuwlaat R, Wilczynski N, Navarro T, et al. Interventions for enhancing medication adherence. *Cochrane Database Syst Rev*. 2014;11:CD000011. <https://doi.org/10.1002/14651858.CD000011.pub4>.
- Free C, Phillips G, Galli L, et al. The effectiveness of mobile-health technology-based health behaviour change or disease management interventions for health care consumers: a systematic review. *PLoS Med*. 2013;10(1) <https://doi.org/10.1371/journal.pmed.1001362> e1001362.
- Fede DA, Cushing CC, Fritz A, Amaro CM, Ortega A. Mobile health interventions for improving health outcomes in youth: a meta-analysis. *JAMA Pediatr*. 2017;171(5):461–469. <https://doi.org/10.1001/jamapediatrics.2017.0042>.
- Badawy SM, Barrera L, Sinno MG, Kaviany S, O'Dwyer LC, Kuhns LM. Text messaging and mobile phone apps as interventions to improve adherence in adolescents with chronic health conditions: a systematic review. *JMIR MHealth UHealth*. 2017;5(5):e66. <https://doi.org/10.2196/mhealth.7798>.
- Lee J-A, Choi M, Lee SA, Jiang N. Effective behavioral intervention strategies using mobile health applications for chronic disease management: a systematic review. *BMC Med Inf Decis Mak*. 2018;18(1):12. <https://doi.org/10.1186/s12911-018-0591-0>.
- Lau R, Stevenson F, Ong BN, et al. Achieving change in primary care—effectiveness of strategies for improving implementation of complex interventions: systematic review of reviews. *BMJ Open*. 2015;5(12) <https://doi.org/10.1136/bmjopen-2015-009993>.

- e009993.
14. Ross J, Stevenson F, Lau R, Murray E. Factors that influence the implementation of e-health: a systematic review of systematic reviews (an update). *Implement Sci*. 2016;11(1):146. <https://doi.org/10.1186/s13012-016-0510-7>.
 15. Grol R, Grimshaw J. From best evidence to best practice: effective implementation of change in patients' care. *Lancet Lond Engl*. 2003;362(9391):1225–1230. [https://doi.org/10.1016/S0140-6736\(03\)14546-1](https://doi.org/10.1016/S0140-6736(03)14546-1).
 16. Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. Diffusion of innovations in service organizations: systematic review and recommendations. *Milbank Q*. 2004;82(4):581–629. <https://doi.org/10.1111/j.0887-378X.2004.00325.x>.
 17. May CR, Mair F, Finch T, et al. Development of a theory of implementation and integration: normalization process theory. *Implement Sci IS*. 2009;4:29. <https://doi.org/10.1186/1748-5908-4-29>.
 18. May C, Finch T. Implementing, embedding, and integrating practices: an outline of normalization process theory. *Sociology*. 2009;43(3):535–554. <https://doi.org/10.1177/0038038509103208>.
 19. May CR, Johnson M, Finch T. Implementation, context and complexity. *Implement Sci*. 2016;11:141. <https://doi.org/10.1186/s13012-016-0506-3>.
 20. Kosse RC, Bouvy ML, de Vries TW, Koster ES. Effect of a mHealth intervention on adherence in adolescents with asthma: a randomized controlled trial. *Respir Med*. 2019;149:45–51. <https://doi.org/10.1016/j.rmed.2019.02.009>.
 21. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health*. 1999;89(9):1322–1327.
 22. Marcano Belisario JS, Greenfield G, Car J, Gunn LH. Smartphone and tablet self management apps for asthma. *Cochrane Database Syst Rev*. 2013;11:CD010013. <https://doi.org/10.1002/14651858.CD010013.pub2>.
 23. Kosse RC, Bouvy ML, de Vries TW, et al. mHealth intervention to support asthma self-management in adolescents: the ADAPT study. *Patient Prefer Adherence*. 2017;11:571–577. <https://doi.org/10.2147/PPA.S124615>.
 24. Kosse RC, Bouvy ML, de Vries TW, Koster ES. Evaluation of a mobile health intervention to support asthma self-management and adherence in the pharmacy. *Int J Clin Pharm*. 2019;41(2):452–459. <https://doi.org/10.1007/s11096-019-00798-3>.
 25. May C, Rapley T, Mair FS, et al. Normalization process theory on-line users' manual, Toolkit and NoMAD instrument. Published <http://www.normalizationprocess.org>; 2015.
 26. Luetsch K, Qudah B. The impact of mHealth applications on patient - health care provider relationships - findings from a scoping review. *Res Soc Adm Pharm*. 2018;14(8):e48. <https://doi.org/10.1016/j.sapharm.2018.05.098>.
 27. Slovinsky DJ, Malvey DM, Neigel AR. A model for mHealth skills training for clinicians: meeting the future now. *mHealth*. 2017;3:24. <https://doi.org/10.21037/mhealth.2017.05.03>.
 28. Mossialos E, Courtin E, Naci H, et al. From “retailers” to health care providers: transforming the role of community pharmacists in chronic disease management. *Health Policy*. 2015;119(5):628–639. <https://doi.org/10.1016/j.healthpol.2015.02.007>.
 29. Crawshaw J, Auyeung V, Ashworth L, Norton S, Weinman J. Healthcare provider-led interventions to support medication adherence following ACS: a meta-analysis. *Open Heart*. 2017;4(2) <https://doi.org/10.1136/openhrt-2017-000685> e000685.
 30. Kosse RC, Bouvy ML, Belitser SV, de Vries TW, van der Wal PS, Koster ES. Effective engagement of adolescent asthma patients with mobile health-supporting medication adherence. *JMIR Mhealth Uhealth*. 2019;7(3) <https://doi.org/10.2196/12411> e12411.
 31. Murray E, Hekler EB, Andersson G, et al. Evaluating digital health interventions: key questions and approaches. *Am J Prev Med*. 2016;51(5):843–851. <https://doi.org/10.1016/j.amepre.2016.06.008>.
 32. Nkansah N, Mostovetsky O, Yu C, et al. Effect of outpatient pharmacists' non-dispensing roles on patient outcomes and prescribing patterns. *Cochrane Database Syst Rev*. 2010;7:CD000336. <https://doi.org/10.1002/14651858.CD000336.pub2>.
 33. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci*. 2009;4:50. <https://doi.org/10.1186/1748-5908-4-50>.
 34. Michie S, Johnston M, Abraham C, et al. Making psychological theory useful for implementing evidence based practice: a consensus approach. *Qual Saf Health Care*. 2005;14(1):26–33. <https://doi.org/10.1136/qshc.2004.011155>.
 35. May C. Towards a general theory of implementation. *Implement Sci IS*. 2013;8:18. <https://doi.org/10.1186/1748-5908-8-18>.
 36. Ossebaard HC, Van Gemert-Pijnen L. eHealth and quality in health care: implementation time. *Int J Qual Health Care*. 2016;28(3):415–419. <https://doi.org/10.1093/intqhc/mzw032>.