## **ORIGINAL ARTICLE**



## Systematic adaptation of the adherence improving selfmanagement strategy to support breast cancer survivors' adherence to adjuvant endocrine therapy: An intervention mapping approach

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## **Abstract**

**Objective:** Non-adherence to adjuvant endocrine therapy (AET) for breast cancer leads to increased recurrence and mortality risk and healthcare costs. Evidence on feasible, effective AET adherence interventions is scarce. This paper describes the systematic adaptation of the cost-effective adherence improving self-management strategy (AIMS) for patients with HIV to AET for women after breast cancer treatment.

**Methods:** We followed the intervention mapping protocol for adapting interventions by conducting a needs assessment, reviewing target behaviours and determinants, reassessing behaviour change methods and adapting programme content. Therefore, we performed a literature review, consulted behavioural theory and organised nine advisory board meetings with patients and healthcare professionals.

Results: Non-adherence occurs frequently among AET users. Compared to HIV treatment, AET is less effective, and AET side effects are more burdensome. This drives AET treatment discontinuation. However, the key determinants of non-adherence are largely similar to HIV treatment (e.g. motivation, self-regulation and patient-provider relationship); therefore, most strategies in AIMS-HIV also seem suitable for AIMS-AET. Modifications were required, however, regarding supporting patients with coping with side effects and sustaining treatment motivation.

**Conclusion:** AIMS seems to be a suitable framework for adherence self-management across conditions and treatments. Intervention mapping offered a transparent, systematic approach to adapting AIMS-HIV to AET.

#### KEYWORDS

 $adherence, adjuvant\ endocrine\ the rapy,\ breast\ cancer,\ intervention\ mapping,\ physical\ activity,\ self-management$ 

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#### 1 | INTRODUCTION

Breast cancer is the most prevalent cancer in women, with an annual incidence of 14,935 and a 10-year prevalence of 139,029 in the Netherlands (Netherlands Cancer Registry, 2020). Most breast cancers (among 75%) are hormone sensitive (Li et al., 2003), and these women are recommended to use oral adjuvant endocrine therapy (AET) for at least 5 years (Netherlands Cancer Registry, 2017). This reduces mortality by 33% on average but varies largely for each individual (Early Breast Cancer Trialists' Collaborative Group, 2005). However, AET is associated with side effects, including hot flushes, mood swings, fatigue and musculoskeletal symptoms (Condorelli & Vaz-Luis, 2018). Consequently, medication adherence is suboptimal, which is shown in irregular intake (i.e. decreased implementation; Vrijens et al., 2012) and early discontinuation (i.e. non-persistence; Vrijens et al., 2012) in about 50% of patients (Moon et al., 2019; Murphy et al., 2012). This enhances the risk of cancer recurrence, mortality and increases healthcare costs in case of secondary cancer (Early Breast Cancer Trialists' Collaborative Group, 2005; Font et al., 2019; Hershman et al., 2011; McCowan et al., 2013). Hence, supporting AET adherence has important benefits for women using AET and for the (cost)effectiveness of healthcare.

A recent systematic review of studies examining the effectiveness of interventions promoting AET adherence in women with breast cancer found no evidence of feasible, acceptable and (cost)effective interventions (Ekinci et al., 2018). However, interactive in-person delivered behavioural theory-based interventions were shown to be promising for supporting AET adherence (Ekinci et al., 2018). Across conditions, successful adherence interventions appeared to be based on theory and various behaviour change methods (BCMs), targeted to patients with adherence difficulties and focused on habits and prompts to perform the behaviour (Nieuwlaat et al., 2014; Oberjé et al., 2013). One meta-analysis studying potential effective components of medication adherence interventions across various treatments found that combining in-person support with electronic monitoring and feedback on adherence seemed particularly effective (Demonceau et al., 2013). Additionally, reducing side effects of AET may help to prevent nonpersistence. Physical activity has shown to be an effective strategy to improve quality of life and reduce AET side effects (Allen et al., 2014; Campbell et al., 2019; Duijts et al., 2012). Hence, a behavioural intervention supporting adherence directly, and indirectly via promoting physical activity, may be particularly beneficial in the treatment of AET. An emerging body of evidence supports the benefits of electronic monitoring (e.g. a wearable activity tracker) to stimulate physical active behaviour in the general population (Laranjo et al., 2021), as well as in women with breast cancer (Hartman et al., 2018; Pudkasam et al., 2021; Singh et al., 2020).

The Adherence Improving self-Management Strategy (AIMS) is an in-person delivered adherence intervention that utilises electronic monitoring and feedback as core BCMs (de Bruin et al., 2005). AIMS has been developed in collaboration with HIV patients and healthcare providers (HCPs), is based on empirical literature and behavioural theories, addresses multiple behavioural determinants (knowledge,

motivation and self-regulation) and has been designed to be delivered by trained HCPs during routine clinical visits. Hence, AIMS incorporates the above-mentioned key ingredients of a successful adherence intervention. AIMS is delivered by nurses during regular clinical visits and consists of the following steps: (1) discussing patients knowledge on adherence and providing targeted information on adherence, (2) goal setting and talking about patients motivation for medication intake behaviour, (3) comparing the set goal with patients medication intake behaviour (patient has used an electronic monitoring device to track his medication intake. In the consultation, nurse presents a report of patients medication intake to the patient) and (4) definitive goal setting for medication intake behaviour, action and coping planning (de Bruin et al., 2005). The AIMS intervention has been applied to promote HIV treatment adherence and demonstrated to be feasible to deliver, acceptable to patients and HCPs, effective in improving adherence and clinical outcomes (e.g. a reduction of treatment failure of 61%) and cost-saving (de Bruin et al., 2005, 2010, 2017; Wijnen et al., 2018). Instead of developing a new intervention, we presumed AIMS to be a suitable intervention to promote AET adherence. Besides, adapting evidence-based interventions makes science

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ABLE 1 Steps of intervention mapping for adaptation		
Step	Questions to be answered	
Needs assessment and logic model of the problem	<ul> <li>What are the consequences of non-adherence to AET for health-related quality of life and survival?</li> <li>Which behaviours and determinants are related to (non)-adherence to AET?</li> <li>Which environmental (i.e. organisational, communal and societal) factors can influence the behaviour?</li> <li>What are the key differences compared to the HIV population?</li> </ul>	
2. Logic model of change and matrices	<ul> <li>Which behavioural outcomes and performance objectives need to be added, deleted or adapted for the new population?</li> <li>Which determinants and change objectives need to be deleted, added or revised for the new population and new performance objectives?</li> </ul>	
3. Methods and practical applications	<ul> <li>Are the methods and strategies of the original programme applicable for the new population?</li> <li>Are the methods feasible and practical in the new community context?</li> <li>Which methods need to be added or modified?</li> </ul>	
4. Programme components and delivery channels	<ul> <li>Given the modifications in objectives and/or methods, what content should remain the same, should be adapted or deleted and what content should be added?</li> </ul>	

potentially more efficient and cumulative (Copeland et al., 2021). Since the original AIMS intervention does not address side effect management, an adaptation of the AIMS intervention would be required.

The adaptation of an existing intervention should be undertaken systematically and be reported in detail (Copeland et al., 2021). Intervention mapping (IM) is a commonly used framework for developing (Rammant et al., 2021; van Noort et al., 2020) and adapting (Boekhout et al., 2017; Jans et al., 2020) behavioural interventions. The process of adapting interventions to a new context, population and/or behaviour includes six steps (Bartholomew, 2011); our study centres upon Steps 1–4, presented in Table 1.

## 2 | METHODS

This study was approved by the Medical ethical committee Arnhem-Nijmegen (reference number: NL 2019-5517). To answer the questions in each step of the protocol, a literature review was performed, multiple iterative advisory board sessions with patients and HCPs were held, and a rapid feasibility test for key elements that could pose implementation difficulties was performed (Figure 1).

## 2.1 | The AIMS intervention

The AIMS intervention was developed for patients with HIV. The intervention consists of five building blocks that are shown in Figure 2. In each building block, a set of different BCMs is applied. A detailed description of the original intervention rationale, components and protocol can be found elsewhere (de Bruin et al., 2005). In this paper, we describe the steps that were undertaken to adapt AIMS-HIV to AET users and present the rationale, components and protocol of the adapted AIMS intervention for AET users (AIMS-AET) in Section 3.

In the adaptation process to AIMS-AET, we added the discussion and electronic monitoring of physical activity behaviour as a core strategy for managing side effects. We expect the adapted

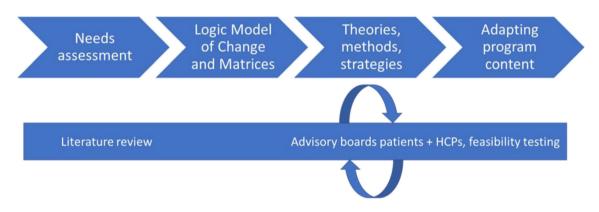
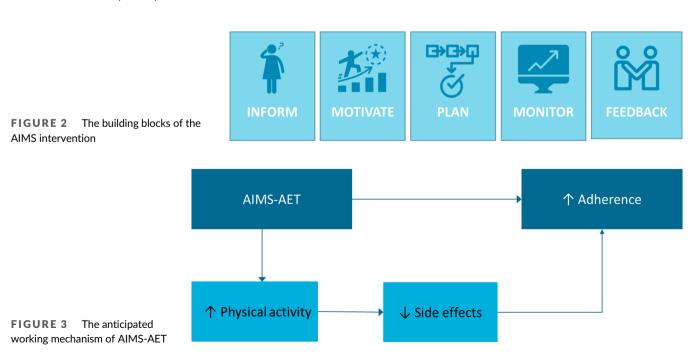


FIGURE 1 The adaptation process of AIMS-HIV to AIMS-AET



intervention to increase medication adherence by using the building blocks and strategies of the original AIMS intervention. Additionally, we expect the intervention to decrease experienced side effects by increasing physical activity. A diminished side effect burden should contribute to medication adherence, too. The anticipated working mechanism of AIMS-AET is shown in Figure 3.

## 2.2 | Literature review

A literature search was performed in July 2019 in the databases PsycINFO, Medline and Embase to identify literature about the determinants of (non)-adherence to AET with keywords for breast cancer, adjuvant endocrine therapy, adherence and persistence and determinants (see Appendix A for search details).

Firstly, we searched for reviews. Secondly, we added the keywords qualitative, focus group\* and interview\* to identify qualitative literature on (modifiable) determinants of (non-)adherence. Finally, we identified studies presenting quantitative data on determinants of (non-)adherence published after the search date of the latest review (December 2017). Only articles in full text and in English language were included. Articles describing interventions, protocols and results of randomised controlled trials (RCT) and conference abstracts were excluded. All articles were screened on title/abstract. Full-text articles of potentially relevant articles were assessed for eligibility. Data on sociodemographic and behavioural determinants of (non-)adherence and barriers and facilitators were extracted from eligible articles. Extracted data were then compared with the AIMS-HIV intervention to identify similarities and discrepancies.

## 2.3 | Advisory board meetings

The researchers recruited eight HCPs from Radboudumc (n=4) and two collaborating community hospitals, Rijnstate hospital (n=2) and Bernhoven hospital (n=2), to participate in advisory board meetings. Subsequently, the HCPs in two hospitals approached patients who currently received AET or who recently discontinued AET, were able to understand Dutch and were willing to come to the hospital for the advisory board meeting. We aimed to recruit a sample with a variety in social economic status, ethnicity, age, family situation and state of adherence. Nine patients (eight from Radboudumc and one from Bernhoven) agreed to participate and gave informed consent.

The advisory board meetings were led by one researcher (AJ) and supported by at least one other researcher (MdB, JD) and lasted between 98 and 180 min. We asked participants to reflect on determinants of non-adherence found in the literature, to discuss their relevance for this context and to identify missing determinants. We described the intended AIMS modules and asked participants to reflect on the selected intervention strategies, materials and BCMs from their personal or professional experience. In particular, we were interested in intervention feasibility, compatibility with goals and values, perceived complexity and relative advantage (Rogers, 2003).

All sessions were audiotaped, input from participants was discussed within the research group, findings were compared with literature, and modifications were incorporated in the intervention programme. In the next step, the adapted programme was presented in another advisory board meeting with different participants. In total, three iterative advisory board meetings with HCPs were performed between September 2019 and December 2019, and six iterative advisory board meetings with patients were performed between September 2019 and July 2020.

## 2.4 | Patient representative

A patient representative from the Dutch breast cancer organisation gave input on the design of the study, the interpretation of the results and how they were used to adapt AIMS. The Dutch breast cancer organisation was reimbursed for this work.

## 2.5 | Feasibility testing of the electronic devices

In the AIMS-AET intervention, electronic devices were proposed as self-monitoring tools to measure medication adherence (medication button: MEMS Adherence Hardware Button, Aardex) and physical activity (activity tracker). There is also substantive evidence that using such trackers as part of (counselling) interventions is effective in supporting behaviour change (Demonceau et al., 2013; Hartman et al., 2018; Pudkasam et al., 2021; Singh et al., 2020). In order to quickly pre-test the user-friendliness of the selected devices, five patients who had participated in advisory board meetings were asked to use the devices for 4 weeks. Three of them agreed to test the devices. Additionally, the patient representative was asked to participate in the feasibility testing. Two different types of activity trackers (Garmin vivofit 4 and Yamax EX210) were sent to four participants, each to be used for 2 weeks sequentially, after which participants were interviewed by phone about their user experiences by one researcher (AJ). Participants were asked to reflect upon the attractiveness, clarity of usage and efficiency of the devices. Further, they were interviewed about their perception of the data output of the devices, their motivation to use the device and any other remarks (see the interview guide in Appendix E). Interviews were audiotaped and lasted between 24 and 59 min.

## 3 | RESULTS

## 3.1 | Literature review

The literature search (search date: 8 July 2019) yielded 1374 unique results, including 17 eligible reviews. Additionally, 129 qualitative studies were identified, of which 20 were eligible. Further, we identified 220 quantitative articles (published between December 2017 and July 2019), of which nine met the inclusion criteria. The flow

#### **TABLE 2** Determinants related to AET adherence

#### Determinants related to AET adherence

Positively associated with adherence	Negatively associated with adherence
Demographics	
Being married or having a higher income (Paranjpe et al., 2019)	Aged <40/50 years or >65/75 (Moon, Moss-Morris, Hunter, Carlisle, & Hughes, 2017; Paranjpe et al., 2019), higher baseline body mass index (BMI) (Hagen et al., 2019)

#### Knowledge

Being able to explain working mechanism of AET (Farias et al., 2017), receiving timely and relevant information about working mechanism, efficacy and side effects of AET (Brett et al., 2018; Humphries et al., 2018; Iacorossi et al., 2018; Moon, Moss-Morris, Hunter, & Hughes, 2017; Pellegrini et al., 2010; van Londen et al., 2014; Verbrugghe et al., 2017)

Thinking that one doses of AET does not affect efficacy (Harrow et al., 2014), not receiving information about side effects and how to manage them, inadequate timing of information about side effects or receiving too much info at one time (Bluethmann et al., 2017; Brett et al., 2018; Verbrugghe et al., 2017)

#### Motivation, attitude and beliefs

Beliefs: necessity beliefs: Tamoxifen keeps me alive, fear of death and repeated cancer treatment (lacorossi et al., 2018; Moon, Moss-Morris, Hunter, & Hughes, 2017); strong necessity and control beliefs or belief in benefits outweigh concerns (Cahir, Dombrowski, et al., 2015; Harrow et al., 2014; lacorossi et al., 2018; Lambert, Balneaves, Howard, Chia, & Gotay, 2018; Moon, Moss-Morris, Hunter, & Hughes, 2017)

Outcome expectations: having positive outcome expectations for AET (Bluethmann et al., 2017; Cahir, Dombrowski, et al., 2015)

Emotions: fear of cancer recurrence (Cahir, Dombrowski, et al., 2015; lacorossi et al., 2018), positive emotions towards AET (happy to take medication, protection, control) (Harrow et al., 2014; Humphries et al., 2018; lacorossi et al., 2018; Lambert, Balneaves, Howard, Chia, & Gotay, 2018; Moon, Moss-Morris, Hunter, & Hughes, 2017), anticipated regret (Cahir, Dombrowski, et al., 2015)

Risk perception: belief to be at high risk for recurrence (Lambert, Balneaves, Howard, Chia, & Gotay, 2018)

Intentions and goals: being intrinsically motivated for AET, having strong intention to take AET for 5 years to prevent cancer recurrence (Cahir, Dombrowski, et al., 2015)

Beliefs: burden of side effects outweigh benefits (Moon, Moss-Morris, Hunter, & Hughes, 2017), prioritising quality of life over survival/recurrence risk (Brett et al., 2018; Lambert, Balneaves, Howard, Chia, & Gotay, 2018; van Londen et al., 2014), being sceptical about the benefits of AET, conflicting beliefs regarding disadvantages and advantages (Brett et al., 2018; Moon, Moss-Morris, Hunter, & Hughes, 2017), having concerns about long-term use of AET (toxicity, medication use in general, physical changes, wish for child-bearing) (Brett et al., 2018; Hackett et al., 2018; lacorossi et al., 2018; Moon, Moss-Morris, Hunter, & Hughes, 2017; Pellegrini et al., 2010)

Emotions: negative emotions towards AET (reminder of cancer, discomfort) (Hackett et al., 2018; Iacorossi et al., 2018; Moon, Moss-Morris, Hunter, Carlisle, & Hughes, 2017)

Risk perception: risk perception decreases over time (Brett et al., 2018; Lambert, Balneaves, Howard, Chia, & Gotay, 2018), belief to be at low risk for recurrence (Brett et al., 2018; Moon, Moss-Morris, Hunter, & Hughes, 2017)

#### Subjective norms

Witness significant others as role model in taking medication (Hackett et al., 2018), extrinsic motivation by family (Cahir, Dombrowski, et al., 2015)

Discomfort of taking AET in front of others (lacorossi et al., 2018)

## Self-efficacy and self-regulation

High levels of coping self-efficacy and self-determination (Cahir, Dombrowski, et al., 2015), organisation and planning around AET (Cahir, Dombrowski, et al., 2015), using reminders to prevent forgetting medication intake (lacorossi et al., 2018), exhibit or talk about action and coping planning, self-monitoring and develop a routine (Cahir, Dombrowski, et al., 2015)

Stopping for a shorter period for drug holiday/relief/unintentionally (Brett et al., 2018; Lambert, Balneaves, Howard, Chia, & Gotay, 2018)

## Managing side effects

Using coping strategies adopting healthy lifestyles to tolerate medication or that help alleviate side effects (Ahlstedt Karlsson et al., 2019; Brett et al., 2018; Farias et al., 2017; Lambert, Balneaves, Howard, Chia, & Gotay, 2018; Moon, Moss-Morris, Hunter, & Hughes, 2017; van Londen et al., 2014)

Advice of doctors on how to manage side effects do not help (Bluethmann et al., 2017), perceived side effects or higher impact of side effects on daily functioning (Bluethmann et al., 2017; Brett et al., 2018; Moon, Moss-Morris, Hunter, & Hughes, 2017), side effects occur frequently, severely and unpredictably, leading to a restriction of social activities (Brett et al., 2018)

#### Social support

Making use of various sources for social support (informational, emotional, instrumental, appraisal) (Toledo et al., 2019), social support from peers (Humphries et al., 2018; Toledo et al., 2019; Verbrugghe et al., 2017), social support from family and friends (Brett et al., 2018; Humphries et al., 2018; lacorossi et al., 2018; Lambert, Balneaves, Howard, Chia, & Gotay, 2018)

Experiencing a lack of validation of side effects and/or support (Lambert, Balneaves, Howard, Chia, & Gotay, 2018; Moon, Moss-Morris, Hunter, & Hughes, 2017; Pieters et al., 2019; van Londen et al., 2014; Verbrugghe et al., 2017; Yamamoto et al., 2015)

#### TABLE 2 (Continued)

Relationship and communication with the HCP

Shared decision making (Farias et al., 2017), social support of HCP (Brett et al., 2018; Farias, 2015; Humphries et al., 2018; lacorossi et al., 2018; van Londen et al., 2014), trust in HCP, relying on doctors' opinion, good patient–HCP relationship (Brett et al., 2018; Cahir, Dombrowski, et al., 2015; Farias, 2015; Harrow et al., 2014; lacorossi et al., 2018; Lambert, Balneaves, Howard, Chia, & Gotay, 2018), receiving psychological support (lacorossi et al., 2018), continuation of care: having appointments with the same HCP always (lacorossi et al., 2018)

Perceiving a lack of interest and support in side effects from HCPs (Brett et al., 2018; van Londen et al., 2014)

Note: The results are organised in a similar way to the behavioural determinants also used in AIMS-HIV (de Bruin et al., 2005).

charts of these searches and the article references are included in Appendix B.

# 3.2 | IM Step 1: Needs assessment and logic model of the problem

# 3.2.1 | Consequences of non-adherence to AET for health and quality of life

Not taking AET consistently (28% to 72% use less than 80% of their medication) and the premature treatment discontinuation (non-persistence: 31%–73% before Year 5) were found to be associated with a 71% higher risk for cancer recurrence, 52% less time until cancer recurrence and a 26%–49% decreased survival (Chirgwin et al., 2016; Font et al., 2019; Hershman et al., 2011; McCowan et al., 2013; Murphy et al., 2012). Consistent intake of medication appeared to decline by treatment duration (Moon et al., 2019).

Up to 84% of patients experience side effects that may reduce QoL (Boehm et al., 2009; Ferreira et al., 2019; Ganz et al., 2016; Kumar, 2018; Lambert, Balneaves, Howard, & Gotay, 2018; Moon, Moss-Morris, Hunter, Carlisle, & Hughes, 2017; Paranjpe et al., 2019). Examples of side effects are hot flushes, impaired sleep, fatigue and musculoskeletal pain (Couzi et al., 1995; Pan et al., 2018; Sousa et al., 2017). Women who reported (severe) side effects were four to five times more likely to discontinue AET early compared to women without side effects (Milata et al., 2018; Moon, Moss-Morris, Hunter, Carlisle, & Hughes, 2017). Side effects may also reduce physical activity levels, cause difficulties with (close and sexual) relationships, decrease self-confidence and cause social isolation (Brett et al., 2018). This may induce a downward spiral, where women conclude that the potential benefits of the treatment outweigh the costs, leading to non-persistence (Moon, Moss-Morris, Hunter, & Hughes, 2017).

# 3.2.2 | Behaviours and determinants related to (non-)adherence to AET

Our literature review revealed that both implementation and nonpersistence are influenced by patients' demographics, knowledge, motivation, subjective norms, self-regulation, management of side effects and support. Table 2 provides an overview of the demographic and behavioural determinants associated with adherence identified in the literature. A narrative description of these results is provided in Appendix C.

## 3.2.3 | Key differences and similarities with AIMS-HIV

There are many similarities in the determinants that drive adherence to AET and adherence to antiretroviral therapy for HIV: Adherence is influenced by demographic variables, with a lower SES or not having a partner being associated with non-adherence (García & Côté, 2003; Paranipe et al., 2019). Further, personal beliefs and perceptions about the medication and the illness play a substantial role. If personal risk perception is low or medication beliefs are negative. adherence is found to be lower (García & Côté, 2003; Moon, Moss-Morris, Hunter, Carlisle, & Hughes, 2017). Next, subjective norms show some effects on adherence: If the patient perceives that important people in her personal environment believe in the medication or want the patient to take the medication, adherence is found to be higher (Cahir, Guinan, et al., 2015; García & Côté, 2003). Selfefficacy, skills and self-regulation play an important role in adherence: If the patient perceives herself to be capable to adhere to treatment and possesses about the skills to perform and regulate her behaviour, odds for adherence are much higher compared to having a low self-efficacy (Cahir, Guinan, et al., 2015; García & Côté, 2003). Last, social support and the relationship between HCP and patient seem to be of undeniable influence on adherence: Patients with sufficient social support and a good relationship with their HCP usually show better adherence (Brett et al., 2018a; García & Côté, 2003; Toledo et al., 2019). A key difference, however, is that while the efficacy of the lifelong HIV treatment is reflected in a non-detectable viral load and improved health, AET is an adjuvant treatment, typically prescribed for 5 years, with uncertainty about personal effectiveness and a possible side effect burden, contributing to higher rates of non-persistence (Cahir, Guinan, et al., 2015; Moon, Moss-Morris, Hunter, & Hughes, 2017; Paranjpe et al., 2019; Verbrugghe et al., 2017).

## 3.3 | IM Step 2: Logic model of change

**Behavioural outcomes** specify which behaviour patients should demonstrate after the intervention (Bartholomew, 2011). The main behavioural outcome in AIMS-AET is the regular and continued use of

medication (i.e. patient takes the right doses of medication in the right interval), similar to AIMS-HIV. Our literature review and advisory board meetings showed that, also maintaining motivation for treatment persistence is a problem. Therefore, AIMS-AET emphasises persistence (i.e. patient continues with the treatment for the prescribed

**TABLE 3** Performance objectives, determinants and change objectives in AIMS-AET

	Important and modifiab	Important and modifiable determinants with change objectives				
Performance objectives (PO)	Knowledge,	Attitude	Outcome expectancies	Self-regulation and self-efficacy	Subjective norm and perceived social support	
PO1. Patient takes medication consistently and correctly and discusses personal strategies for optimal medication intake and for difficult situations regarding medication intake with HCP	K1.1 Patient recalls reasons for taking medication daily and what dosage of medication should be taken K1.2 Patient knows that an interruption in medication intake can reduce efficacy of treatment K1.3 Patient is aware of own adherence behaviours, barriers, facilitators and context	A1.1 Patient recalls risk for suboptimal efficacy of medication increases by missed doses and treatment interruptions A1.2 Patient expresses positive affect towards daily intake and correct dosage of medication A1.3 Patient perceives adherence as relevant for achieving personal goals	OE1.1 Patient states that she expects that medication is most effective by taking the right dosages, at the right time with the right interval OE1.2 Patient states that she expects that a routine helps her to support optimal medication adherence	SS1.1 Patient makes a personalised action and coping plan and a self-monitoring strategy for medication intake SS1.2 Patient expresses confidence in using the medication consistently and correctly, according to her set goal SS1.3 Patient expresses confidence in overcoming barriers in medication adherence SS1.4 Patient demonstrates that adherence has become low-effort, automatically activated behaviour	SN1.1 Patient perceives that the HCP wants to support her to take the medication correctly and consistently SN1.2 Patient perceives that her family/friends wan her to take her medication consistently and correctly	
PO2. Patient persists to AET and copes effectively with side effects	K2.1 Patient recalls working mechanism of AET K2.2 Patient recalls where she can find trustworthy information about AET online related to her problems K2.3 Patient recalls type, intensity and volume of physical activity that can help manage side effects	A2.1 Patient perceives herself as susceptible for cancer recurrence and perceives this risk to decrease by almost half after 5 years of AET A2.2 Patient perceives the risk to die from breast cancer as disturbing her personal goals A2.3 Patient outweighs perceived benefits (links personal goals with treatment) over concerns/ perceived barriers regarding persisting to AET	OE2.1 Patient expects that side effects of AET are manageable with physical activity and the support of HCP + family/ friends and her own ability of development/ growing self-management skills	SS2.1 Patient makes a personalised coping plan to manage side effects and worries SS2.2 Patient demonstrates (growing) confidence to discuss treatment burden with her partner, in particular relational/sexual complaint SS2.3 Patient makes a personalised plan for performing physical activity including minimal one goal, an action and coping plan and a self-monitoring strategy	SN2.1 Patient perceives that the HCP wants to support her in persistence to treatment, recognises her problems and wants to help her develop coping strategies	

duration) and coping with side effects (i.e. patient is able to deal with and overcome problems caused by adverse effects of the treatment. Patient makes use of effective strategies to deal with difficulties and asks for help if necessary) as a behavioural outcome besides correct and consistent intake of medication.

Performance objectives specify which sub-behaviours patients should show after the intervention in order to achieve the behavioural outcomes (Bartholomew, 2011). Table 3 (left column) provides an overview of the performance objectives for both behavioural outcomes (medication intake and persistence). We added new performance objectives for the second behavioural outcome: persistence. At the same time, we removed the behavioural outcome and performance objectives regarding treatment initiation from AIMS-HIV. Advisory board sessions with HCPs and patients revealed that this performance objective was too complex due the following reasons: First, the advice for AET depends on a set of demographic and tumour-related factors and is therefore not equal for every patient. Second, most HCPs use the online tool PREDICT to calculate and discuss the gain of AET with their patients; however, each HCP uses slightly different communication strategies to inform patients about their personal BC recurrence risk and gain of AET. Targeting the performance objectives regarding treatment initiation would have meant to include a standardised, effective strategy to discuss the personal gain of AET using PREDICT. Third, most patients receive information on AET already during previous treatment with radiotherapy or chemotherapy. Since our literature review showed that too much information at one time is rather contra productive (Brett et al., 2018), we chose to only focus AIMS-AET on patients that already made the decision to start treatment.

Change objectives specify which outcomes on determinant level patients should demonstrate after the intervention (Bartholomew, 2011). By acquiring change on determinant level, the desired performance objectives should be met. The determinants knowledge and awareness, motivation (as a result of attitude, subjective norm and perceived behavioural control) and self-regulation targeted by AIMS-HIV could be incorporated in AIMS-AET. Essential differences include the delivery to women only, the higher burden of side effects and a potential decrease in risk perception over time. Table 3 provides an overview of the change objectives that belong to the different performance objectives.

# 3.4 | IM Steps 3 and 4: Theories, methods and strategies and adaptation of programme content

The next step in the IM protocol is to identify **BCMs** that are likely effective in achieving the change objectives described above. For example, for the determinant knowledge, we formulated the change objective K1.1 Patient recalls reasons for taking medication daily and what dosages of medication should be taken and use, among others, the BCM using imagery to acquire this objective, by facilitating information processing. For each BCM, so-called parameters reflect the conditions under which the BCM is most effective. For the example here, the

method using imagery comes with the parameters that images need to be familiar to the patient as analogies to a less familiar process. This means that when applying this BCM in an intervention, it is important to use simple images to support the understanding of a more complex process. The main aim of IM Steps 3 and 4 is thus to identify a series of BCMs for the intervention programme that cover all the change objectives described in Table 3. All these methods need to be applied correctly (i.e. taking into account their parameters of use) in the final intervention materials in order to achieve the change objectives and ultimately the behavioural outcomes.

The AIMS-HIV intervention is composed of trained HCPs discussing adherence and self-management with patients during routine clinic visits. This conversation is supported by a brief counselling protocol and visualisations that help the HCP and patient discuss and remember more complex issues and follow the counselling protocol. In addition, the patient uses an electronic medication monitor to self-monitor her own medication intake. In the adapted AIMS-AET, also physical activity monitoring is included, since this has been identified as an important strategy to prevent and cope with side effects. The counselling protocol, visual materials and discussion of the results from electronic monitoring include a series of BCMs that represent the active content of AIMS. Table 4 shows all the BCMs selected for AIMS-AET that were either directly adopted from AIMS-HIV or additionally selected from the BCM taxonomy (Kok et al., 2016).

The next step is to develop the practical intervention materials—such as the counselling protocol, the illustrations and the electronic monitors—in which all these BCMs from Table 4 are adequately applied to the change objectives. The advisory board meetings had a key role in evaluating the clarity of the text and figures, the acceptability of the electronic monitors and the feasibility and attractiveness of the intervention as a whole. Firstly, we briefly describe the key input from the advisory board meetings and then illustrate how all evidence, theory and input from the advisory board were translated into the practical intervention materials. The results of the advisory board sessions are shown in Table 5. The intervention protocol and materials of the first intervention session are shown in Table 6 (the protocol of the second intervention session is included in Appendix D).

### 3.5 | Results advisory board meetings

We organised three separate advisory board meetings with HCPs (n=8; four nurse practitioners, three medical oncologists and one case manager. Two were male and six were female) and six with patients (n=9; median age 50 years, range 31–66 years; 50% high education, 30% moderate education, 10% low education, 10% missing data; median work hours/week 25, range 0–36 h; median AET duration 2 years—range from 1 to 5 years, one participant stopped in the fourth year of AET).

We discussed the following key themes in the advisory board meetings: keeping up the motivation for AET, difficulties to address sexual complaints, feedback about images used in the AIMS intervention, dealing with worries and side effects, self-monitoring of physical

**TABLE 4** Behaviour change methods and parameters to acquire the change objectives in AIMS-AET (Kok et al., 2016)

Behavioural Outcome 1	Consistent and correct medication intake	
Determinant and change objectives	Behaviour change methods with definition	Parameters of use: In order for the methods to work, consider that
Knowledge and awareness	Using imagery—using artefacts that have a similar appearance to some subject	Images need to be familiar to the patient as analogies to a less familiar process
K1.1 Reasons for taking medication	Individualisation—provide opportunity to ask questions	Make sure to use personal messages that respond to a patient's needs
K1.2 Effects of medication interruption	Discussion—encourage consideration of a topic in open informal debate	Make sure to listen to the patient to ensure that the correct schemas are activated
K1.3 Awareness of own adherence behaviour	Self-monitoring of behaviour—prompt the person to keep a record of specified behaviour(s)	The monitoring must be of a specific behaviour (i.e. not a physiological state or health outcome). The data must be interpreted and used. The reward must be reinforcing to the patient
	Feedback—give information to individual regarding the extent to which they are accomplishing learning, performance or desired outcomes	Feedback needs to be individualised, follow the behaviour in time and be specific
Attitude A1.1 Risk awareness suboptimal	Consciousness raising—provide information about the causes, consequences and alternatives for a problem or a problem behaviour	Must quickly be followed by increase in problem-solving ability and self-efficacy
medication intake A1.2 Positive affect towards adherence	Framing—use gain-framed messages emphasising the advantages of performing the healthy behaviour	Requires high self-efficacy expectations
A1.3 Adherence and personal goals	Motivational interviewing—provide a collaborative, goal- oriented style of communication with particular attention to the language of change; create an atmosphere of acceptance and compassion	Requires a supportive relationship between client and professional combined with the evocation of patient change talk
Outcome expectancies OE1.1 Expecting treatment to be	Consciousness raising—provide information about the causes, consequences and alternatives for a problem or a problem behaviour	Must quickly be followed by increase in problem-solving ability and self-efficacy
most effective with adherence OE1.2 Expecting a routine would support adherence	Motivational interviewing—provide a collaborative, goal- oriented style of communication with particular attention to the language of change; create an atmosphere of acceptance and compassion	Requires a supportive relationship between client and professional combined with the evocation of patient change talk
Self-efficacy and skills SS1.1 Coping planning SS1.2 Confidence in	Goal setting—prompt planning what the patient will do, including a definition of goal-directed behaviours that result in the target behaviour	Requires commitment to the goal; goals should be difficult but available within the individual skill level
adherence SS1.3 Confidence in overcoming barriers	Participation—assure high-level engagement of the patient in problem solving, decision making and change activities, with highest level being control by the patient	Requires willingness by the HCP to accept the patient as having a high level of influence; requires appropriate motivation and skills of the patient
to adherence SS1.4 Adherence becomes a habit	Self-monitoring of behaviour—prompt the patient to keep a record of specified behaviour(s)	The monitoring must be of the specific behaviour. The data must be interpreted and used. The reward must be reinforcing to the patient
	Planning coping responses—get the patient to identify potential barriers and how to overcome these	Requires identification of high-risk situations and practice of coping response
	Implementation intentions—prompt making if-then plans that link situational cues with responses that are effective in attaining goals or desired outcomes	Requires existing positive intention
	Reattribution training—help the patient to reinterpret previous failures in terms of unstable attributions and previous successes in terms of stable attributions	Requires counselling to make unstable and external attributions for failure
	Cue altering—teaching people to change a stimulus that elicits or signals a behaviour	Requires existing positive intention
		(Continues)

(Continues)

## TABLE 4 (Continued)

Behavioural Outcome 1	Consistent and correct medication intake	
Social norm and perceived social support SN1.1 Support of HCP SN1.2 Support of family/friends	Mobilising social support—combines caring, trust, openness and acceptance with support for behavioural change	Positive support needs to be available in the environment
Behavioural Outcome 2 F	Persistence	
Knowledge and awareness K2.1 Working mechanism of AET. K2.2 Find information about AET K2.3 Physical activity to manage side effects	Using imagery—use artefacts that have a similar appearance to some subject  Individualisation—provide the opportunity to ask questions  Discussion—encouraging consideration of a topic in open informal debate	Images need to be familiar to the patient as analogies to a less familiar process  Make sure to use personal communication/messages that respond to a patient's needs  Make sure to listen to the patient to ensure that the correct schemas are activated
Attitude A2.1 Cancer recurrence risk	Belief selection—.use messages to strengthen positive beliefs, weaken negative beliefs and introduce new beliefs	Make sure to investigate the attitudinal, normative and efficacy beliefs of the patient before choosing the beliefs on which to intervene
perception A2.2 Risk of cancer and personal goals A2.3 Benefits and	Consciousness raising—provide information about the causes, consequences and alternatives for a problem or a problem behaviour	Must quickly be followed by increase in problem-solving ability and self-efficacy
disadvantages of AET	Framing—use gain-framed messages emphasising the advantages of performing the healthy behaviour	Requires high self-efficacy expectations
	Using imagery—use artefacts that have a similar appearance to some subject	Images need to be familiar to the patient as analogies to a less familiar process
Outcome expectancies OE2.1 Expecting that side effects are manageable	Planning coping responses—get the patient to identify potential barriers and how to overcome these	Requires identification of high-risk situations and practice of coping response
	Mobilising social support—combines caring, trust, openness and acceptance with support for behavioural change	Positive support needs to be available in the environment
Self-efficacy and skills SS2.1 Coping plan SS2.2 Confidence to discuss treatment burden SS2.3 Plan for physical	Goal setting—prompt planning what the patient will do, including a definition of goal-directed behaviours that result in the target behaviour	Requires commitment to the goal; goals should be difficult but available within the individual skill level
	Participation—assure high-level engagement of the patient in problem solving, decision making, and change activities, with highest level being control by the patient	Requires willingness by the HCP to accept the patient as having a high level of influence; requires appropriate motivation and skills of the patient
activity	Self-monitoring of behaviour—prompt the patient to keep a record of specified behaviour(s)	The monitoring must be of the specific behaviour. The data must be interpreted and used. The reward must be reinforcing to the individual
	Planning coping responses—get the patient to identify potential barriers and how to overcome these	Requires identification of high-risk situations and practice of coping response
	Implementation intentions—prompt making if-then plans that link situational cues with responses that are effective in attaining goals or desired outcomes	Requires existing positive intention
	Reattribution training—help the patient to reinterpret previous failures in terms of unstable attributions and previous successes in terms of stable attributions	Requires counselling to make unstable and external attributions for failure
	Feedback—give information to individual regarding the extent to which they are accomplishing learning, performance or desired outcomes	Feedback needs to be individual, follow the specific behaviour in time and be specific
Social norm and perceived social support SN2.1 Support of HCP in persistence	Mobilising social support—combines caring, trust, openness and acceptance with support for behavioural change	Positive support needs to be available in the environment

 TABLE 5
 Key feedback and adaptations from advisory board sessions

Patient 4 'I think making up the balance is good' Patient 6 'Me, too. It can be in the beginning or later in the treatment' Patient 4 'You come back once a year, look shortly at this, has this changed? Are there other new issues?'  Patient 9 'Once I had a talk with another HCP. And she asked me if I experienced problems with sex, my HCP had not asked that. I appreciated that. That's part of it, this are problems you can have.
she asked me if I experienced problems with sex, my HCP had not asked that. I appreciated that.
Probably my HCP did not dare to ask. It is one of the most important side effects'
Patient 4 'Awareness that you should not take it nonchalant I never received this kind of information, it is very handy to provide this. It is a very clear image'. Patient 5 and Patient 6 agree
Patient 9 'To me this feels like support. It is very important that there is the atmosphere to talk about things (side effects)' Interviewer: 'What could help in persisting to AET?' Patient 2 'Exercising () Even though I am tired, I exercise anyway, after this I feel relaxed () I can pass the threshold because I know how I will feel after (exercising)' HCP 2 'I say by time we will see which problems you will have and refer to our information folder We also ask what are you afraid of? What could you do? I think we already do this very much, only we do not let the patient write it down' HCP 1 'I say go and experience it (treatment/side effects), it can also just go well. If it does not, then we talk whether the advantages outweigh the side effects But yes, it is good to be extra alert and ask questions about that (worries/problems)'
Patient 4 'Oh this is very good. This is motivating. I think it is also a good idea to keep a diary. Then you get more insights in why something succeeds or not. And then you can tackle this'. Patient 3 agrees. Patient 5 'I think you only have to use the diary. I believe that this (the pedometer) might motivate but I do not want such a thing' HCP 2 'I already see many people with a pulse pedometer or an app But I also advice it. Then you can see a graphic, well show it once to me. It is funny to see that In the future we could all incorporate it in the electronic patient file'
H1 'Awareness. I am very curios (to see) with what (reports) people will come with' HCP 2 'It might feel controlling. I am very curious if

### TABLE 6 Practical application of AIMS-AET (intervention protocol and materials for Session 1)

#### Session 1: First intervention session with patient

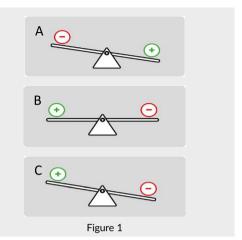
## Step 1: Making up the balance. Change objectives: A2.2, A2.3

Behaviour change methods: Belief selection, using imagery

#### Protocol steps

- 1.1 Nurse asks patient how she is looking towards AET using an image of a balance scale (benefits outweigh disadvantages, benefits and disadvantages weigh equal, disadvantages outweigh benefits; figure 1)
- 1.2 Nurse asks for disadvantages first. Nurse pro-actively asks for sexual complaints. Then, nurse asks for benefits and how those benefits relate to the personal goals of the patient
- 1.3 After recognition of negative beliefs, nurse puts emphasise on strengthening existing positive beliefs by linking personal goals with beliefs and introduces new positive heliefs

Figure 1: An image of three motivational weight scales: (a) benefits outweigh disadvantages, (b) benefits and disadvantages weigh equal, (c) disadvantages outweigh benefits



#### Step 2: Refreshing knowledge. Change objectives: K2.1, K2.2, A2.1

Behaviour change methods: Individualisation, using imagery, discussion, consciousness raising, framing

#### Protocol steps

- 2.1 Nurse asks patient what she remembers about the working mechanism of AET.

  Nurse complements patients' answers and/or corrects misconceptions using figure 2
- 2.2 Nurse asks patient what she remembers about the reasons for duration of AET.
  Nurse complements patients' answers and/or corrects misconceptions using figure 3
- 2.3 Nurse provides the opportunity to ask questions to patient. Nurse asks patient to reflect on the given information.
- 2.4 Nurse asks patient where she collects information about AET. Nurse provides trustworthy online sources for information about AET and related problems to the patient, if needed
- Figure 2: The working mechanism of AET. A cancer cell (red circle). This cell possesses a receptor (black half round) for the female hormone oestrogen (blue oval). The stop board represents AET.
- Figure 3: An image of the protection that AET provides per year of usage. Each year, up to Year 5, the protection increases, for example, the average risk for the cancer recurrence decreases (indicated with the green umbrellas). For some women, AET is prescribed for a longer period, up to 10 years (the big dark grey umbrella). The protection after 5-year usage remains up to 15 years (the white umbrella)

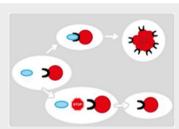


Figure 2

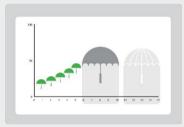


Figure 3

Step 3: Increasing self-efficacy—making a plan for how to deal with challenges of AET. Change objectives: OE2.1, SS2.1, SS2.2, SS2.3, SN2.

Behaviour change methods: Feedback, participation, planning coping responses, mobilising social support, goal setting, self-monitoring of behaviour, implementation intentions

#### Protocol steps

- 3.1 Nurse asks patient to identify the one or two most disturbing/urgent problems (e.g. side effects or worries) she perceives regarding AET
- 3.2 Nurse asks patient to identify possible solutions for this problem by asking what solutions have worked before, by providing a list of solutions that has worked for others, and suggesting the use of social support when relevant
- 3.3 Nurse introduces physical activity as a core-strategy to cope with or prevent side effects of AET. Nurse uses figures 4 and 5 to show which types of, intensity level and amount of physical activity helps to alleviate specific side effects. Nurse provides the outcomes of self-monitoring physical activity behaviour to the patient (see an example in figure 6). Nurse asks her to reflect upon her behaviour and set a goal for physical activity behaviour
- 3.4 Nurse asks patient to write down their challenges, solutions including physical activity goals, and IF THEN plans in her personal coping plan

<u>Figure 4</u>: The issues related to AET (left column) that can be influenced positively by different types of physical activity (upper row)



Figure 4

### TABLE 6 (Continued)

## Session 1: First intervention session with patient

<u>Figure 5</u>: The amount of physical activity that is recommended in order to experience benefits on health and wellbeing

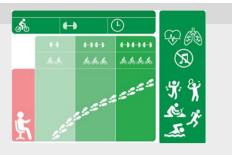


Figure 5

Step 4: Increase knowledge about the association of daily usage and efficacy of AET. Change objectives: K1.1, K1.2, A1.1, A1.2 Behaviour change methods: Individualisation, using imagery, discussion, consciousness raising, framing

#### Protocol steps

- 4.1 Nurse asks what the patient knows about how AET should be taken and to provide reasons for daily and timely intake
- 4.2 Nurse completes answers and/or corrects misconceptions using figure 6
- 4.3 Nurse asks patient to reflect upon given information

Figure 6: The level of AET (tamoxifen) in the body, related to its efficacy

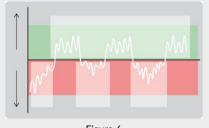


Figure 6

**Step 5: Motivation for medication intake.** Change objectives: A1.3, OE1.1, OE1.2 Behaviour change methods: Goal setting, motivational interviewing

#### Protocol steps

- 5.1 Nurse presents six example images of medication self-monitoring outcomes to the patient (see examples in figures 7a and 7b), which represent different patterns of medication intake behaviours—from high until low targets
- 5.2 Nurse asks patient to set a goal for how she prefers to take medication. Nurse then asks why patient prefers to take medication in this way and did not choose a lower goal to identify motivating factors. Subsequently, nurse asks why patient chose this goal and not a higher goal to identify barriers
- 5.3 Nurse shows figure 6 again and asks patient in which way the medication will work in her body with her set goal
- 5.4 Nurse states the identified values of the patient from Step 1 and asks how they relate to this goal
- Figure 7a: An example of a medication adherence report (high target). The y-axis provides the time of the day, the x-axis provides the date. Each blue dot indicates a consumed dosage. In this report, medication had been taken every day at a similar time
- <u>Figure 7b</u>: An example of a medication adherence report (low target). The grey bars indicate missed dosages. In this report, medication had been taken every without a routine, every day at another time. At several days, medication had been missed

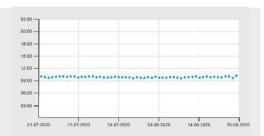
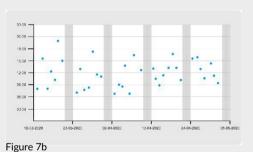


Figure 7a



Step 6: Evaluation of medication intake behaviour. Change objectives: K1.3, OE1.2, A1.3, SS1.2

Behaviour change methods: Feedback, self-monitoring of behaviour, reattribution training, motivational interviewing

#### Protocol steps

- 6.1 Nurse presents outcomes of self-monitored medication intake behaviour to the patient and ask her to reflect upon her result. Several options are possible:
- 6.1.1 Patient selected a high target and reached her target. Nurse provides positive feedback. In case of any late intake or missed dosage, nurse aims to find out the reason together with the patient
- 6.1.2 Patient selected an adequate target but the report is disappointing. Nurse controls first if patient used medication adherence button adequately. Nurse accepts a possible defensive reaction of the patient and reflects the feelings. If patient accepts, nurse looks together with patients for reasons of missed dosages. Nurse puts focus on positive intake periods and asks what went different there compared to days with missed dosages
- 6.1.3 Patient selected a lower target, but intake behaviour is better than she expected. Nurse compliments patient and tries to find out reasons for low self-assessment
- 6.1.4 Patient selected a low target and indeed does take medication sub-optimal. Nurse compliments patient for adequate self-assessment. Nurse asks patient why patient succeeds to take medication in some periods and in others not. Nurse aims to increase motivation for medication adherence by putting emphasise on the future and setting graded tasks

### TABLE 6 (Continued)

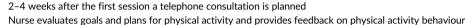
#### Session 1: First intervention session with patient

Step 7: Coping planning to prevent sub-optimal medication adherence. Change objectives: SS1.1, SS1.2, SS1.3, SN1.1, SN1.2 Behaviour change methods: Planning coping responses, mobilising social support, implementation intentions, cue altering

#### Protocol steps

- 7.1 Nurse assesses patients' barriers to consistent medication intake
- 7.2 Nurse asks patient to think of possible solutions for these barriers. If the patient cannot think of sufficient solutions herself, nurse asks for permission to introduce strategies that helped other women in comparable situations (these examples include cue altering strategies like setting reminders for medication intake)
- 7.3 Nurse asks the patient to formulate an IF THEN plan for routinely medication intake
- 7.4 Nurse assesses with figure 8 how much trust the patient has in the goal she set for medication intake, with the help of the plans she made

<u>Figure 8</u>: An image to assess the level of trust someone has in performing a specific behaviour with numbers from 1 to 10



Session 2: Follow-up session after 3-6 months. For the content of Session 2, see Appendix D



Figure 8

activity and monitoring medication adherence, goal setting and action planning. In Table 5, we present key themes, the adaptations we made regarding the given feedback and some illustrative quotes.

# 3.6 | Results feasibility testing: Field testing of self-monitoring devices

In order to determine user-friendliness, we asked four patients to test the medication button and two different types of activity trackers for 4 weeks. All users reported that the medication registration button was easy to use. Four participants thought that it would be of added value to discuss the report from the button with the HCP. For one participant, it felt a little bit like being controlled. We concluded that the medication button was user friendly and accepted by the target group.

All participants had a clear preference for the Garmin vivofit 4 over the Yamax EX210 because it is worn around the wrist, it can be connected to an app that makes it possible to have an overview of steps for a longer period and it has more functions. Participants reported to perceive more awareness of physical activity, and some felt motivated to increase their number of daily steps. We therefore chose to use the Garmin vivofit 4 in AIMS-AET.

## 3.7 | Intervention protocol and materials

Table 6 shows the intervention protocol and materials for the first AIMS-AET session. The first session consists of seven protocol steps. In each step, different change objectives should be met by the appropriate application of the BCMs we chose. Therefore, we translated the BCMs into the protocol and materials, taking the parameters of use and the feedback from the advisory board meetings into account. The protocol for the follow-up session can be found in Appendix D.

### 4 | DISCUSSION

This paper highlights important considerations necessary to for adapting the AIMS-HIV intervention for supporting adherence to the context and treatment of women with breast cancer using AET. The context, mode of delivery, behaviours and determinants of nonadherence of HIV patients are comparable to AET users. Therefore, the behaviour change methods, counselling steps and figures used in AIMS-HIV could be adapted to AET adherence. Since non-persistence and coping with side effects are major problems in patients receiving AET, we created an additional module for this in AIMS-AET. In the new module, we applied the strategies to change behaviour from the original intervention (influence the determinants knowledge, motivation and self-regulation and make use of self-monitoring). We also added physical activity as an additional behaviour to the adapted intervention. These additional modules can be bolted on the original AIMS modules and could well be used for the adaptation of AIMS in other treatments.

IM served as a valuable framework in the adaptation process that guarantees a thoughtful, systematic approach to understanding behaviours, using behavioural theory and obtaining input from endusers (patients) and implementers (HCPs). This should increase the chances that AIMS-AET is feasible, acceptable and effective for AET adherence. In this process, we first studied literature to investigate which behaviours and determinants were related to (non-)adherence to AET in female breast cancer survivors. We took an efficient approach by identifying the most recent literature reviews, which provided a good overview of AET adherence determinants, and then sought for novel quantitative and additional qualitative studies. The qualitative literature added important contextual information to the quantitative literature but also more detailed insights in exact treatment beliefs and barriers relevant to women using AET. Advisory board meetings with patients and HCPs allowed us to iteratively incorporate feedback of the target group, which supports intervention

acceptability and implementation. Since we decided to add an extra module for treatment motivation and coping with side effects, this process was more time consuming.

Adaptation of existing health behaviour change interventions to novel treatments and populations is yet uncommon in the health behaviour literature. This study shows one way of accomplishing this. We believe this contributes to a more cumulative literature (as opposed to having numerous different frameworks and interventions), provided that it is done systematically and reported thoroughly (Copeland et al., 2021). At present, the AIMS-AET intervention is evaluated in a pilot RCT. A process evaluation will help us to examine the acceptability and feasibility of intervention delivery in clinical practice, to further refine the intervention and to identify in which manner the intervention matches user preferences (Mulder et al., 2016). We will also explore potential effects on AET adherence and physical activity.

In conclusion, this study showed that it is executable to systematically adapt an existing medication adherence intervention and emphasises that the IM framework is a valuable tool to plan, carry out and transparently report the intervention adaptation process. The mix of quantitative and especially qualitative literature, combined with the input from implementers and end users, was sufficient for guiding the intervention adaptation process. The adaptation of proven effective and feasible health behaviour change interventions, from one domain or population to another, may be a more efficient and cumulative strategy as opposed to always developing new interventions.

## **CONFLICT OF INTEREST**

The authors have no conflicts of interest to declare.

## DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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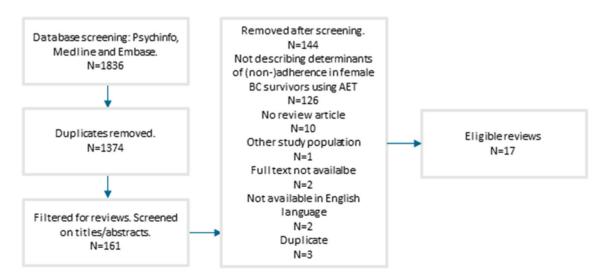
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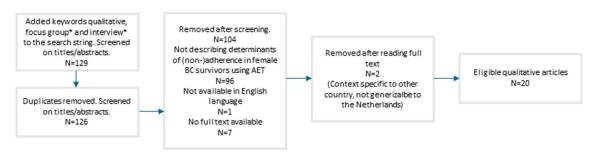
#### APPENDIX A: SEARCH STRING LITERATURE REVIEW

(("breast neoplasms" or "breast cancer" or "breast tumor") and ("adjuvant endocrine therapy" or "oral endocrine therapy" or "hormone therapy" or "hormonal therapy" or "antihormonal therapy" or "tamoxifen" or "aromatase inhibitor").ab and (adherence or nonadherence or non-adherence or compliance or non-compliance or noncompliance or persistence or nonpersistence or non-persistence or discontinuation or cessation or initiation or engagement).af and (determinant\* or barrier\* or facilitator\* or attitude or "social norm" or "social influence" or self-efficacy or intention\* or skill\* or belief\*)).af.

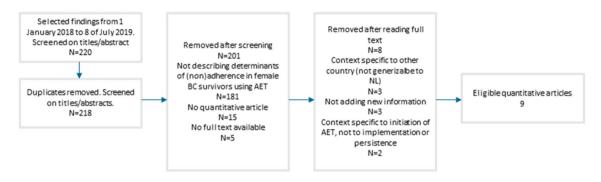
#### APPENDIX B: FLOW CHARTS LITERATURE REVIEW



APPENDIX B1 Flow chart reviews. Identified as eligible: (Accordino & Hershman, 2013; Banning, 2012; Cahir, Guinan, et al., 2015; Chlebowski et al., 2014; Gotay & Dunn, 2011; Lambert, Balneaves, Howard, & Gotay, 2018; Mausbach et al., 2015; McCowan & Thompson, 2012; Miaskowski et al., 2008; Milata et al., 2018; Moon, Moss-Morris, Hunter, Carlisle, et al., 2017; Murphy et al., 2012; Paranjpe et al., 2019; Puts et al., 2014; Sawesi et al., 2014; Van Liew et al., 2014; Wassermann & Rosenberg, 2017)



APPENDIX B2 Flow chart qualitative articles. Identified as eligible: (Bluethmann et al., 2017; Brett et al., 2018; Cahir, Dombrowski, et al., 2015; Farias, 2016; Farias et al., 2017; Hackett et al., 2018; Harrow et al., 2014; Humphries et al., 2018; Hurtado-de-Mendoza, Cabling, et al., 2019; Iacorossi et al., 2018; Lambert, Balneaves, Howard, Chia, et al., 2018; Moon, Moss-Morris, Hunter, & Hughes, 2017; Pellegrini et al., 2010; Pieters et al., 2019; Samuel et al., 2017; Toledo et al., 2019; van Londen et al., 2014; Wheeler et al., 2015; Wouters et al., 2013; Yamamoto et al., 2015)



**APPENDIX B3** Flow chart quantitative articles. Identified as eligible: (Brett et al., 2018b; Cabling et al., 2018; Hagen et al., 2019; Hurtadode-Mendoza, Carrera, et al., 2019; Kroenke et al., 2018; Kuba et al., 2018; Lee & Min, 2018; Yin, Harrell, et al., 2018; Yin, Warner, et al., 2018)

## APPENDIX C: A NARRATIVE REVIEW OF DETERMINANTS RELATED TO AET ADHERENCE

## Demographic factors

Younger women (<40/50) tend to be less adherent compared to women aged older than 50, most likely due to fertility concerns or problems in coping with menopausal symptoms (Lambert, Balneaves, Howard, & Gotay, 2018; Moon, Moss-Morris, Hunter, Carlisle, & Hughes, 2017; Paranipe et al., 2019). Additionally, lower adherence was observed in older women (>65/75) (Moon, Moss-Morris, Hunter, Carlisle, & Hughes, 2017; Paranipe et al., 2019). In this group, women who adhered to AET were more likely to be married or have a higher income (Paranjpe et al., 2019). For other demographic factors like cultural background, the evidence is not conclusive (Moon, Moss-Morris, Hunter, Carlisle, & Hughes, 2017). Higher baseline body mass index (BMI) was negatively associated with persistence (Hagen et al., 2019). This might be due to a more rapid decrease of oestrogen by AET in patients with a higher BMI inducing more severe side effects (Hagen et al., 2019).

### Knowledge

Women value receiving detailed information about AET prior to initiation by their HCPs (Lambert, Balneaves, Howard, & Gotay, 2018). Insufficient information and conflicting advice lead to misconceptions about AET regarding the working mechanism, the prescription regime and the necessity and efficacy of therapy (Lambert, Balneaves, Howard, Chia, & Gotay, 2018). Most women appreciate risk information regarding the chance for survival or recurrence with and without treatment but statistics are often misinterpreted (Berry, 2004; Pieters et al., 2019). A wrong interpretation of the individual risks might lead to doubts about the necessity of AET and support non-persistence (Moon, Moss-Morris, Hunter, & Hughes, 2017). Further, adherence is negatively affected by thinking that one missed dose does not compromise treatment effects, not knowing how to take the medication properly and not knowing arguments supporting the long treatment duration (Brett et al., 2018; Lambert, Balneaves, Howard, & Gotay, 2018). Information about side effects and how to cope with them facilitates adherence (Verbrugghe et al., 2017). Last, the timing and amount of information at one time impacts the ability of processing and understanding information (Brett et al., 2018).

#### Motivation and beliefs

The motivation to adhere to AET is a result of a decisional balance between necessity or positive beliefs and neutral beliefs or concerns, for example, if necessity beliefs outweigh concerns, adherence increases and vice versa (Lambert, Balneaves, Howard, & Gotay, 2018; Moon, Moss-Morris, Hunter, Carlisle, & Hughes, 2017; Moon, Moss-Morris, Hunter, & Hughes, 2017; Paranipe et al., 2019; Verbrugghe et al., 2017). Necessity beliefs represent the perceived valuation of treatment like protection from recurrence, a feeling of control, future health and positivity and are highly influenced by the fear of cancer recurrence or death (Lambert, Balneaves, Howard, & Gotay, 2018; Moon, Moss-Morris, Hunter, Carlisle, & Hughes, 2017; Paranipe et al., 2019). If women have a family, they are usually driven by the responsibility to stay alive for their children and/or their partner. (lacorossi et al., 2018; Moon, Moss-Morris, Hunter, & Hughes, 2017) Concerns reflect the worries and perceived disadvantages of AET like worries about dependence on treatment (e.g. the fear of forgetting a dose that might cause cancer), side effects and having an impaired QoL, the perception that AET is a barrier to regain normalcy, general disliking medication, being sceptical about the efficacy of AET, the belief that nothing can be gained after 2 years of treatment, long-term adverse effects, the impact of treatment on fertility and the duration of treatment (Ahlstedt Karlsson et al., 2019: Brett et al., 2018; Lambert, Balneaves, Howard, & Gotay, 2018; Paranjpe et al., 2019). Women hold complex beliefs about AET, and the decision to discontinue might be the result of misguided beliefs about side effects experiences (Moon, Moss-Morris, Hunter, & Hughes, 2017). Experiencing a goal conflict (goal to finish therapy, but treatment conflicts with everyday life) was found to be associated to non-persistence-vice versa, setting the goal of preventing cancer recurrence and therefore setting the intention to adhere to the prescribed treatment duration were facilitators for taking medication correctly and persist (Cahir, Dombrowski, et al., 2015). Interestingly, positive emotions regarding AET were found to increase adherence, while negative emotions regarding AET lead to patients attributing their symptoms to AET, and were found to decrease adherence (Moon, Moss-Morris, Hunter, Carlisle, & Hughes, 2017; Moon, Moss-Morris, Hunter, & Hughes, 2017; Paranipe et al., 2019). Positive emotions, cognitive self-talk and self-management strategies are important facilitators for adherence, especially when barriers (e.g. concerns and side effects) are present.

Women who prioritise short time QoL (feeling of relieve from side effects, regaining normalcy) above their perceived protection from AET show higher rates of non-persistence (Brett et al., 2018). Further, a lower perceived risk for cancer recurrence is associated with non-persistence (Lambert, Balneaves, Howard, Chia, & Gotay, 2018; Paranjpe et al., 2019; Pieters et al., 2019).

Risk perception for recurrence might reduce over time, which could explain a decrease in adherence over time. As a form of coping, women might choose to avoid thoughts about breast cancer and risk of recurrence, which were found to be associated to lower adherence (Lambert, Balneaves, Howard, Chia, & Gotay, 2018). Less anticipatory emotions (e.g. feeling fear in the present about the possible recurrence of cancer in the future) were found to be associated with less AET adherence intentions (Hurtado-de-Mendoza, Carrera, et al., 2019). Facilitators of adherence are accepting circumstances, recognising positive sides of the disease/going through this process and seeing that they already have been managing worse circumstances (lacorossi et al., 2018).

A quantitative study has tested the theory of planned behaviour to explain adherence intentions to AET (Hurtado-de-Mendoza, Carrera, et al., 2019). It revealed that ambivalence regarding AET, reflected by mixed emotions and doubts, negatively affected AET adherence intentions.

## Self-efficacy and skills, planning and self-regulation

Higher amounts of perceived self-efficacy in patient–HCP interaction, medication taking and adherence are associated with adherence (Hurtado-de-Mendoza, Carrera, et al., 2019; Lambert, Balneaves, Howard, & Gotay, 2018; Moon, Moss-Morris, Hunter, Carlisle, & Hughes, 2017; Paranjpe et al., 2019). A lower general self-efficacy was also associated to non-adherence (Kuba et al., 2018). Feeling involved and empowered in AET decision making was associated to better adherence (Lambert, Balneaves, Howard, & Gotay, 2018).

Non-adherent women demonstrate difficulties establishing routines for taking AET, struggle to refill and self-monitor their prescriptions (Cahir, Dombrowski, et al., 2015; Paranipe et al., 2019). Consistently, establishing routines for AET taking, using reminders, visual cues, storage strategies and coping planning for barriers to medication intake support adherence (Ahlstedt Karlsson et al., 2019; Lambert, Balneaves, Howard, & Gotay, 2018). Further, developing coping strategies to deal with side effects like adapting lifestyle, exercising, meditating and practical advices like removing layers of clothes can enhance adherence (Farias, 2015; Lambert, Balneaves, Howard, & Gotay, 2018; Moon, Moss-Morris, Hunter, & Hughes, 2017; van Londen et al., 2014). Women who were persistent and taking medication consistently and correctly used behaviour regulation strategies like action planning and coping planning, self-monitoring and establishing a routine, while a the focus on short-term outcomes was found as self-regulation strategy in non-persistent women (Cahir, Dombrowski, et al., 2015).

## Subjective norm

Lower prescriptive norms (what do people commonly think someone should do) were found to be associated with lower AET adherence intentions and vice versa (Hurtado-de-Mendoza, Carrera, et al., 2019).

Non-persistent women were referring to examples of women who survive without AET and died despite AET (Cahir, Dombrowski, et al., 2015).

#### Environmental factors related to (non-)adherence

#### Social support

Social support can influence adherence negatively and positively and is particular important for persistence (Moon, Moss-Morris, Hunter, Carlisle, & Hughes, 2017; Paranipe et al., 2019; Toledo et al., 2019). A prospective study in Norway found that lower social support by family and friends in the first treatment year was related to non-persistence (Hagen et al., 2019). Women have the tendency not wanting to complain about their symptoms at home and feel misunderstood because their social environment expects them to be healthy again (Ahlstedt Karlsson et al., 2019). Insufficient validation of side effects and treatment burden by family and friends is a barrier to persistence (Moon, Moss-Morris, Hunter, Carlisle, & Hughes, 2017; Paranipe et al., 2019; van Londen et al., 2014), wherein the spouse plays the most important role (Verbrugghe et al., 2017). Vice versa, adequate social support is a facilitator to persistence. Persistent women combine different sources of social support (Kroenke et al., 2018; Toledo et al., 2019; Yamamoto et al., 2015); support by peers can be a valuable source (Humphries et al., 2018; Toledo et al., 2019; Verbrugghe et al., 2017). Importantly, high levels of social support from the HCP can reduce the negative impact of low or moderate personal social support (Kroenke et al., 2018).

While emotional support, for example, understanding, kindness, not feeling alone is found to be the most important factor for persistence, practical support can help in tackling forgetfulness (partner reminds of taking pills) (lacorossi et al., 2018).

### Patient-HCP relationship

The patient–HCP relationship is an important determinant of AET adherence. Consistently, the quality of this relationship was found to influence adherence significantly. Specifically, value of HCP opinion, frequency of HCP communication, self-efficacy in patient–HCP communication, shared decision making and person-centred communication are associated with increased levels of adherence (Farias, 2015;

Lambert, Balneaves, Howard, & Gotay, 2018; Moon, Moss-Morris, Hunter, Carlisle, & Hughes, 2017), while poorer patient-oncologist relationship and a lack of support with symptom management were associated with non-adherence (Lambert, Balneaves, Howard, Chia, & Gotay, 2018; Paranipe et al., 2019). Frequent communication about AET (Lambert, Balneaves, Howard, & Gotay, 2018), the ability to ask questions and recognition of side effects are facilitators for adherence (Farias, 2015; Moon, Moss-Morris, Hunter, Carlisle, & Hughes, 2017; Verbrugghe et al., 2017).

Literature states that healthcare providers deliver support mainly in the form of information about potential side effects by initiation of AET (Milata et al., 2018). Being well informed by the HCP about potential side effects enhances adherence (Lambert, Balneaves, Howard, Chia, & Gotay, 2018). Despite, women report that support in managing side effects throughout treatment is lacking and that the support they received was insufficient (Lambert, Balneaves, Howard, Chia, & Gotay, 2018; Milata et al., 2018). Unmet information needs make women seek in other sources, with high chances to find negatively biased information online (Milata et al., 2018).

A perceived lack of interest regarding side effects from the HCP, insufficient validation of side effects and lacking support in side effect management are barriers for adherence (Brett et al., 2018; Moon, Moss-Morris, Hunter, & Hughes, 2017; van Londen et al., 2014; Verbrugghe et al., 2017). Healthcare providers perceive a lack of knowledge about existing management strategies to support women in coping with side effects (Paranjpe et al., 2019). A decision aid to make an informed choice which strategy to choose is missing (Milata et al., 2018). HCPs might be unaware about all side effects since standardised screening is absent—it was pointed out that patients do not report all side effects, in particular hair loss, pain during intercourse and fatigue (Paranjpe et al., 2019).

A quantitative study has analysed the communication between HCPs and patients (Yin, Warner, & Malin, 2018). They found that using verbs that indicate positive communication and stable health conditions were connected to higher persistence as well as talking about ordering prescriptions and making appointments.

## **APPENDIX D: AIMS INTERVENTION SESSION 2**

#### Intervention session 2

#### Step 1: Checking for changes in motivation for treatment persistence

#### Change objectives

A2.3 Patient outweighs perceived benefits (links personal goals with treatment) over concerns/perceived barriers regarding persisting to AET SS2.1 Patient makes a personalised coping plan to manage side effects and worries

#### Behaviour change methods and parameters: Belief selection, using imagery

#### Protocol steps

- 1.1 Nurse asks patient how she is looking towards AET now using figure 1 (balance scales). Several options are possible:
- 1.2.1 Improvement in comparison with last consultation or keeping a positive balance scale: Nurse reinforces what went well
- 1.2.2 Status quo of neutral or negative balance scale. Nurse assesses if new problems occurred or if existing problems worsened and assesses the impact on daily life of the patient. Nurse listens and shows understanding for the difficult situation of the patient
- 1.2.3 Worsening. Nurse assesses reasons for worsening and the impact on daily life of the patient. Nurse listens and shows understanding for the difficult situation of the patient

### Step 2: Evaluation of plan for dealing with challenges of AET

#### Change objectives

- OE2.1 Patient expects that side effects of AET are manageable with physical activity and the support of HCP + family/friends and her own ability of development/growing self-management skills
- SS2.1 Patient makes a personalised coping plan to manage side effects and worries
- SS2.2 Patient demonstrates (growing) confidence to discuss treatment burden with her partner, in particular relational/sexual complaint

**Behaviour change methods:** Feedback, self-monitoring of behaviour, reattribution training, goal setting, planning coping responses, mobilising social support, implementation intentions

#### Protocol steps

- 2.1 Nurse asks how the execution of the plan on how to deal with challenges went
- 2.2 Nurse reinforces success and the overwinning of difficult situations
- 2.3 In case of failing/negative experiences: Nurse assesses reasons
- 2.4 Nurse helps patient to reattribute negative experiences and helps patient to find new solutions and plans if required
- 2.5 Nurse presents results of self-monitoring of physical activity to the patient. Nurse asks patient to interpret her results. Several options are possible:
- 2.5.1 Patient did not yet achieve her goal: Nurse assesses if achieving of the activity goal was not achieved structurally or in specific situations and identifies the reasons. Structural problems—nurse assesses whether a change of the action plan can help to achieve the goal. Barriers—nurse asks patient to think of solutions and to formulate an IF THEN plan for the barriers. Nurse then asks to set a goal for the upcoming period and assesses her trust in achieving her goal using figure 8
- 2.5.2 Patient achieved her goal: Nurse asks patient to set a goal for the upcoming period. Nurse asks questions to stimulate the patient to think about how she can make her behaviour a routine, to think of possible barriers and solutions for barriers

### Step 3: Evaluation of medication intake behaviour

- SS1.1 Patient makes a personalised action and coping plan and a self-monitoring strategy for medication intake
- SS1.2 Patient expresses confidence in using the medication consistently and correctly, according to her set goal
- SS1.3 Patient expresses confidence in overcoming barriers in medication adherence
- SS1.4 Patient demonstrates that adherence has become low-effort, automatically activated behaviour
- SN1.1 Patient perceives that the HCP wants to support her to take the medication correctly and consistently

Behaviour change methods: Feedback, reattribution training, goal setting, planning coping responses, mobilising social support, implementation intentions, Cue altering

## Protocol steps

- 3.1 Nurse presents outcomes of self-monitored medication intake behaviour to the patient and ask her to reflect upon her result. Several options are possible:
- 3.1.1. Patient did not yet achieve her goal: Nurse assesses if achieving of the medication intake goal was not achieved structurally or in specific situations and identifies the reasons. Structural problems—nurse assesses whether a change of the action plan can help to achieve the goal. Barriers—nurse asks patient to think of solutions and to formulate an IF THEN plan for the barriers. Nurse asks patient to assess which reminders and cues can help her to take medication on time. Nurse asks patient to set a medication intake goal for the upcoming period and assesses her trust in achieving her goal using figure 9
- 3.1.2 Patient achieved her goal: Nurse asks patient to set a goal for the upcoming period. Nurse asks questions to stimulate the patient to think about how she can make her behaviour a routine, to think of possible barriers and solutions for barriers

## APPENDIX E: FEASIBILITY TESTING: INTERVIEW GUIDE

### A. Questions about the medication button

#### Attractivity

- 1. What is your general impression of the medication button?
- 2. What do you think about how it looks?

#### Clarity

- 3. How do you use the medication button?
- 4. What do you think about this?
- 5. Is it clear to you how to use it?
  - a. What was necessary for this?
- 6. What did you think about the information you received by the researcher?
  - a. Was it sufficient? Or did you like to know more? (If yes, specify what)
- 7. Where did you store the medication button?
  - Has this changed by time? (If yes, specify when and why)
- 8. Did you experience any barriers in usage?

## Efficiency

- 9. The researcher asked you to press the medication button each time you take your medication. To which extend did you succeed?
- 10. How did you experience to do so?
- 11. How much time and effort did this cost you?
  - a. Did you experience this as burdensome?

#### Motivation

- 12. How did you experience using the medication button?
- 13. Imagine you may borrow this medication button from the hospital, would you use this opportunity?
- 14. For how long would you want to use this medication button?
- 15. In which way would you want to use it?
- 16. Would you advise this button to other patients? (Specify why/why not)

#### Data output

Researcher sends the report of the medication button to the participant and explains what this report shows.

- 17. What do you see here?
- 18. What do you think about what you see?
- 19. What would you think if your nurse would talk about this report with you?

#### General

- 20. Do you think that you behaved differently since the use of this medication button?
- 21. Do you have any other remarks about the medication button?

### B. Questions about the activity trackers

1. In the last 4 weeks, you were asked to use two activity trackers: in the first 2 weeks the Yamax and then the Garmin vivofit 4 for 2 weeks. Which one did you like more and why?

#### Attractivity

- What is your general impression of the Yamax/Garmin vivofit 4?
- 3. What do you think about the how the Yamax/Garmin vivofit looks?
- 4. Is it easy for you to read the display of the Yamax/Garmin vivofit 4?
- 5. For the Garmin vivofit 4, how is it to wear the wrist band (comfortable, or do you experience irritations)?

## Clarity

- 6. How do you use the Yamax/Garmin vivofit 4?
- 7. What do you think about this?
- 8. Is it clear to you how to use the Yamax/Garmin vivofit 4?
  - a. What was necessary to do so?
- 9. What did you think about the information provided by the researcher?
  - a. Was it sufficient? Or would you have liked to know more? (if yes, specify what)
- 10. Where did you store/secure the Yamax/Garmin vivofit 4?
  - a. Has this changed by time? (if yes, specify when and why)
- 11. Which options did you discover within the Garmin vivofit 4?
  - a. Movebar (red balks)

- i. How did this work for you?
- ii. Did you experience an acoustic signal?
- iii. Do you have any idea when the red balks became visible?
- iv. Do you have any idea when the red balks disappeared?
- v. What do you think about this?

### b. Goalsetting for steps

- i. Did you do anything with the function to set a goal for your daily steps?
- ii. Would you like to something with this goalsetting function? (Specify why/why not)
- 12. Did you miss any options within the Garmin vivofit 4?
- 13. Where there options within the Garmin vivofit 4 that were needless?

### Efficiency

- 14. To which extend did you succeed in using the Yamax/ Garmin vivofit 4?
- 15. How much time and effort did the usage cost you?

## Validity

16. Do you have the idea that you have control among the Yamax/Garmin vivofit 4?

### Motivation

- 17. Did you like using the Yamax/Garmin vivofit 4?
- 18. Imagine you may borrow the Yamax/Garmin vivofit 4 from the hospital, would you use this opportunity?
- 19. For how long would you want to use the Yamax/Garmin vivofit 4?
- 20. In which way would you want to use it?
- 21. Would you advise the Yamax/Garmin vivofit 4 to other patients? (Specify why/why not)

### Data output

Researcher sends the report of the Garmin vivofit 4 to the participant and explains what this report shows.

- 22. What do you see here?
- 23. What do you think about what you see?
- 24. What would you think if your nurse would talk about this report with you?

#### General

- 25. Do you think that you behaved differently since the use of the Yamax/Garmin vivofit 4?
- 26. Do you have any other remarks about the Yamax/Garmin vivofit 4?