

Developing and validating a theoretical measure of modifiable influences on hormonal therapy medication taking behaviour in women with breast cancer

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Abstract (200 words)

Objective: Taking adjuvant hormonal therapy for 5-10 years is recommended to prevent breast cancer recurrence in those with estrogen positive disease. Despite proven clinical efficacy many women do not take their hormonal therapy as prescribed. This study reports the development and initial validation of a questionnaire measuring the behavioural determinants of hormonal therapy medication taking behaviour (MTB) based on the Theoretical Domains Framework (TDF).

Design: Women with Stage I-III breast cancer (N=223) completed the questionnaire based on the TDF. The TDF is an integrative framework consisting of 14 domains of behaviour change determinants to inform intervention design.

Main outcome measures: Items were developed from previous research, in-depth patient interviews and consultation with health professionals. Confirmatory factor analysis (CFA) was undertaken to generate the model of best fit.

Results: The final questionnaire consisted of 8 domains and CFA produced a reasonable fit ($\chi^2(810)=942$, $p < 0.001$; RMSEA = 0.03 ; CFI = 0.93 and WRMR=0.91) as well as internal consistency ($r=0.16$ to 0.64). There were adequate levels of discriminant validity for the majority of the domains.

Conclusions: A TDF based measure of the behavioural determinants of MTB was developed. Further research is needed to confirm the reliability and validity of this measure.

Key words: Theoretical Domains Framework, medication taking behaviour, breast cancer, adherence, hormonal therapy

Introduction

Clinical guidelines recommend that women with hormone receptor positive breast cancer receive at least five, and up to 10, years of adjuvant hormonal therapy as a preventative measure for breast cancer recurrence and mortality. (Davies et al., 2011) However, despite the proven clinical efficacy of adjuvant hormonal therapy many women do not take their treatment as recommended. Reduced hormonal therapy exposure due to early treatment discontinuation (non-persistence) or failure to take the correct dosage at the prescribed frequency (non-adherence) is associated with an increased risk of early breast cancer recurrence and mortality.(Barron, Cahir, Sharp, & Bennett, 2013; Chirgwin et al., 2016; Hershman et al., 2011) Rates of non-persistence at 5 years range from 16% to 32% in clinical trials of hormonal treatment and between 31% and 73% in routine clinical settings, while prevalence of non-adherence ranges from 41% to 72%.(Barron, Connolly, Bennett, Feely, & Kennedy, 2007; Murphy, Bartholomew, Carpentier, Bluethmann, & Vernon, 2012)

Despite the high prevalence of hormonal therapy non-persistence and non-adherence little is known about the risk factors associated with hormonal therapy medication taking behaviour (MTB). Recent systematic reviews have identified follow-up care with a general practitioner (compared to follow-up by an oncologist) and experience of treatment side-effects as largely negatively associated with persistence, while taking more medications at baseline has been positively associated with persistence. (Cahir, Guinan, Dombrowski, Sharp & Bennett, 2015; Murphy et al., 2012) These reviews highlighted a critical need to identify potentially modifiable determinants that influence hormonal therapy MTB in order to develop behavioural interventions to improve this behaviour.

The Theoretical Domains Framework (TDF) is an integrative framework of multiple theories of behaviour change designed to assess complex behavioural issues such as MTB and inform intervention design.(Cane, O'Connor, & Michie, 2012; Michie et al., 2005; Michie, Johnston, Francis, Hardeman, & Eccles, 2008) The TDF has recently been validated and refined to include 14 domains of potential behavioural determinants. (Cane et al., 2012). A number of studies have applied the TDF to assess potential behavioural determinants across a range of clinical settings and populations. (Cahir et al., 2014; Penn, Dombrowski, Sniehotta & White, 2013; Dombrowski, et al., 2012; McSherry et al., 2012) However, the majority of these studies have used qualitative interviews which limit the generalisability of the findings. (Francis, O'Connor & Curran, 2012) A small number of TDF based questionnaires have been

developed, which have assessed the behavioural determinants of, for example, smoking cessation in dental healthcare (Amemori, Michie, Korhonen, Murtomaa, & Kinnunen, 2011) and maternal care (Beenstock et al., 2012), patient safety behaviours in hospital (Taylor, Parveen, Robins, Slater, & Lawton, 2013) and healthcare professionals implementation behaviour. (Huijg et al., 2014) The TDF has not been used to develop a questionnaire measuring the behavioural determinants of MTB.

The aim of the current study is to develop a questionnaire measuring the behavioural determinants of hormonal therapy MTB based on the 14 domain version of the TDF (Cane et al., 2012) and to test the psychometric properties of this questionnaire in a sample of women with stage I-III breast cancer prescribed hormonal therapy.

Methods

Development of the TDF questionnaire measuring the modifiable determinants of hormonal therapy MTB

The TDF questionnaire items were developed from previous research by the research team including; (i) a systematic review of the modifiable influences on adjuvant hormonal therapy MTB (Cahir et al., 2015); (ii) in depth interviews with women with stage I-III breast cancer prescribed adjuvant hormonal therapy (Cahir et al., 2014) and; (iii) by review and consultation within the research team.

The systematic review identified potentially modifiable determinants of hormonal therapy MTB in women with breast cancer in routine clinical settings and mapped these determinants to the 14 domains of the TDF. The 14 TDF domains are; *Knowledge; Skills; Memory, Attention and Decision Processes; Behavioural Regulation; Social/professional role and identity; Beliefs about Capabilities; Optimism; Beliefs about Consequences; Intentions; Goals; Reinforcement; Emotion; Environmental Context and Resources; and Social Influences*. Each domain is defined as a group of related theoretical constructs (where constructs are defined as component part of theories, such as ‘attitude’, ‘self-efficacy’, ‘anxiety’). For example, the domain Social Influences includes the constructs social support, group norms, social comparisons and several others and the constructs are grouped together to represent the influences of people on others’ behaviours. (Francis et al., 2012; Michie et al., 2005) In meta-analysis three domains (*Beliefs about Capabilities, Social Influences, and Behaviour Regulation*) were found to be associated with hormonal therapy MTB. However several domains associated with MTB in other disease groups including *Beliefs about Consequences, Intentions, Goals, Social Identity, Emotion* and *Knowledge* which have been reported to influence MTB in other disease groups were not examined.(Cahir et al., 2015)

In-depth interviews were conducted with thirty-one women (14 adherent and persistent, 7 non-adherent and persistent, 10 non-persistent) with stage I-III breast cancer prescribed adjuvant hormonal therapy at two cancer centres in Ireland with the TDF informing the analysis framework. Key enablers for adherent and persistent women, based upon pre-specified criteria, were identified within the domain *Beliefs about Consequences* (breast cancer recurrence), *Intentions* and *Goals* (high-priority), *Beliefs about Capabilities* (side-

effects) and *Behaviour Regulation* (managing medication). Adherent and persistent women strongly believed in the efficacy and necessity of their therapy, were highly motivated and adapted a wide range of coping techniques and support networks to enable them to take their treatment and manage side-effects. Key barriers, based upon pre-specified criteria, were identified within the domain *Behaviour Regulation* (no routine), *Memory, Attention and Decision Processes* (forgetting) and *Environmental Context and Resources* (stressors) for non-adherent and persistent women and *Intentions and Goals* (quality of life), *Behaviour Regulation* (temporal self-regulation), *Reinforcement, Beliefs about Consequences* (non-necessity) and *Social Influences* (clinical support) for non-persistent women. Non-adherence was associated with inadequate medication management techniques and non-persistence was associated with a strong distrust of medication and the health care system, a lack of perceived need for treatment and a preference for a good quality of life with little concern or thought given to future outcomes.(Cahir et al., 2014)

The findings from both the systematic review and qualitative interviews were combined and 9 domains and their related constructs were identified as key domains for the MTB questionnaire.(Cahir et al., 2014; Cahir et al., 2015) (Appendix I) The refined framework for the MTB questionnaire, based on previous research, did not include the domain *Skills* as the only skill proficiency required was to swallow a tablet daily. The domains *Intentions and Goals* and *Reinforcement* were included as one domain (*Intentions and Goals and Reinforcement*) in line with the original 12 domain TDF (*Intentions and Goals*) and *Reinforcement* was included based on the qualitative interviews where goal conflict and goal facilitation and reinforcement were shown to be contingent on each other. (Cahir et al., 2014; Michie et al., 2005) Within the qualitative interviews we found that women who were non-persistent with their hormonal therapy wanted to be finished with their treatment (*Intentions and Goals*) and felt their treatment conflicted with their everyday life and plans (goal conflict). Many women reported an improvement in their quality of life and feeling “back to myself” once they ceased their treatment (*Reinforcement*). (Cahir et al., 2014)

The domain *Optimism* was renamed *Personality* and extended to include other personality constructs, such as resilience which had emerged from the qualitative interviews.(Cahir et al., 2014) The domain *Personality* was included with the domain *Beliefs about Capabilities* as only one key construct “resilience” was relevant to MTB within the domain *Personality* and “resilience” was associated with “coping skills” within the domain *Beliefs about Capabilities*.

This is in line with the original 12 domain TDF where the domain *Optimism* was included in the domain *Beliefs about Capabilities*. (Michie et al., 2005) Similarly, the domain *Emotion* was included with the domain *Beliefs about Consequences* as only one key construct “worry about breast cancer recurrence” was relevant to MTB within the domain *Emotion* and this was associated with outcome expectancies in the domain *Beliefs about Consequences*.

Potential individual validated scales for each construct within each domain were identified from the systematic review on potentially modifiable determinants of hormonal therapy MTB and the broader literature on MTB across other disease groups e.g. action planning, coping planning within the domain *Behaviour Regulation*. (Cahir et al., 2015) The identified individual scales for each construct were reviewed by a health psychologist (SD) and discussed with the broader research team (CC, LS, KB) and a consensus was reached on the measures for each construct. The consensus on the individual scales was informed by the academic literature on the scales, the definition of the constructs and domains as formulated by Michie et al. (Michie et al., 2005) and the specific constructs and domains that emerged from the interviews with women with stage I-III breast cancer prescribed hormonal therapy. (Cahir et al., 2014) For example, the domain *Beliefs about Consequences* and the construct ‘utility of adhering’ is measured by the perceived utility of adhering (efficacy and benefits vs. costs of adhering) subscale of the Adherence Determinants Questionnaire (Appendix I). (DiMatteo et al., 1993) For some domains and their constructs (*Knowledge*- sources of knowledge, *Beliefs about Consequences*-outcome expectancies, *Goals*- Perceived reinforcement and goal conflict facilitation) new questions were developed from the interview data where there was a lack of relevant measures in the literature (Appendix I). (Cahir et al., 2014) For other domains and their constructs measures were adapted from the literature. For example a scale was developed using the health action process approach (HAPA) for the constructs coping self-efficacy and maintenance self-efficacy within the domain *Beliefs about Capabilities*. (Schwarzer, Lippke, & Luszczynska, 2011) (Appendix I)

Participants

Eligible participants were women aged between 18 and 80 years with a diagnosis of stage I-III, oestrogen (ER) or progesterone (PR) receptor positive breast cancer diagnosed 2012-2014, who had received tumour directed surgery and had subsequently filled at least one prescription for oral hormonal therapy (selective estrogen receptor modulator, SERM;

aromatase inhibitor, AI) within one year of breast cancer diagnosis. Participants were identified from St James's Hospital Oncology database which contains detailed demographic and clinical information for all incident breast cancer diagnosed in St James's Hospital Dublin, Ireland. Eligible participants were invited, by post, by their oncologist to take part in the study. Ethical approval was obtained from the Hospital Research Ethics Board, and all participants provided informed consent to participate.

Procedure

Participants were sent the questionnaire booklet by post for self-completion with a stamp addressed envelope. Those who had not returned a questionnaire were sent one reminder letter to complete the questionnaire 2-3 weeks after the initial mailing. The questionnaire consisted of sociodemographic questions, questions and validated scales for measuring the 9 domains and their related constructs and questions relating to participants current hormonal therapy MTB. The hormonal therapy MTB questions asked participants whether or not they were; (i) currently taking their hormonal therapy on a regular basis (adherent and persistent) or; (ii) taking their hormonal therapy but regularly missing doses (non-adherent and persistent) or; (iii) had stopped taking their hormonal therapy (non-persistence) or; (iv) had never taken their hormonal therapy (non-initiators). Participants who had stopped taking their hormonal therapy were also asked how long ago they stopped taking their hormonal therapy and who made the decision to stop taking their hormonal therapy e.g. themselves or their oncologist or doctor or both themselves and their oncologist or doctor. The questionnaire also included the Voils self-report measure of the extent of non-adherence (Voils et al., 2012).

Statistical analysis

Confirmatory factor analysis (CFA) was used to examine whether the items measuring the behavioural determinants of hormonal therapy MTB were a good fit to the TDF. CFA was considered appropriate to test the theoretical framework (TDF) and to establish the initial construct validity of the questionnaire and remove unnecessary or deficient items. Sample size guidance indicated that 200 to 300 participants would be adequate for CFA analysis. (Bryant & Yarnold, 1995). The data was screened and descriptive statistics were examined for all items, prior to data analysis including measures of central tendency, variability and

dispersion (skew, kurtosis) using Stata Version 14 (Stata Corporation, College Station, TX, USA).

CFA was used to test the 9 factor model using weighted least square estimates (WLSMV). (Yu & Muthen, 2002) WLSMV is a robust estimator which does not assume normally distributed variables and provides the best option for modelling categorical or ordered data (Yu & Muthen, 2002). The guidelines for testing the model fit included; (i) a root mean square error of approximation (RMSEA) < 0.06 and; (ii) a comparative fit index (CFI) > 0.90 and; (iii) the weighted root mean square residual (WRMR) < 1.0. (Hooper, Coughlan, & Mullen, 2008; Yu & Muthén, 2002) Post-hoc analysis^a was used to improve the model fit by inspecting modification indices (MIs), standardised residuals (SRs) and by assessing each constructs and related items within the context of the TDF. (Byrne, 2011; Hu & Bentler, 1999) Inter-item correlations were used to test for internal consistency, with values above 0.15 to 0.50 being the optimal range. (Clark & Watson, 1995) The total score or subscale score for validated scales which measured particular constructs within a domain were used to calculate inter-item correlations. Discriminant validity was assessed using Fornell and Larkner's tests. (Fornell & Larkner, 1981) The CFA analysis was undertaken using Mplus Version 7.31.

Results

Descriptive statistics

In total 223 women with stage I-III breast cancer and prescribed hormonal therapy completed the questionnaire on MTB (response rate= 61% , N=367 eligible participants). The average age was 61 years (SD=13.9) and 118 women (54.6%) were married. Sixty-five women (29.7%) had third level education and 60 women (28.4%) were currently employed outside of the home. Missing value analysis indicated that the data was missing at random (< 7% missing data across individual measures) and data was imputed using weighted least squares estimation. (Asparouhov & Muthén, 2010)

One hundred and ninety-three women (88.5%) reported being both adherent and persistent with their hormonal therapy since commencing treatment; 12 women (5.5%) reported missing doses on a regular basis (non-adherent and persistent) and 13 women (6.0%) reported that they had stopped taking their hormonal therapy (non-persistent). No women reported never initiating their treatment. Non-adherent and persistent women and non-persistent women had significantly higher self-reported non-adherence scores (Voils scale) compared to adherent and persistent women ($F(2,196) = 4.72, p = 0.01$). (Table 1).

Confirmatory factor analysis

The initial CFA including the 9 domains showed that the data did not fit the model adequately ($\chi^2(1,559)=2107, p<0.001$; RMSEA=0.04; CFI=0.73 and WRMR=1.25). Post-hoc analysis was undertaken and the individual items and scales within each of the 9 domains and their constructs were examined. The domains *Memory, Attention and Decision Processes* and *Environmental Context and Resources* were highly correlated (>0.85). The domain *Memory, Attention and Decision Processes* was measuring any difficulties women experienced in remembering to take their hormonal therapy and the domain *Environmental Context and Resources* was measuring whether or not women forget to take their treatment when traveling or when there is interference with their normal routine. These two domains were incorporated into one domain *Memory, Attention, Decision Processes and Environment* for MTB.

The measure of medication side-effect coping skills (SECope) was removed from the domain *Beliefs about Capabilities* and the Time Perspective Questionnaire (TPQ) was removed from the domain *Behaviour Regulation*. These measures had coefficients (R-Squared) <0.20 and large standardised residuals (> +/-2.58) which is an indication of a high level of error.

(Hooper et al., 2008) Questions relating to the decision making process about taking hormonal therapy with the patient's oncologist and awareness of hormonal therapy side-effects were removed from the domain *Social Identity* as these items also loaded onto other domains such as *Knowledge* and *Behaviour Regulation*. The domain *Social Identity* retained items related to the role of the oncology-patient relationship only. Within some domains such as *Beliefs about Capabilities*, subscales such as action self-efficacy scale, maintenance self-efficacy scale and recovery self-efficacy error terms were allowed to covary as all 3 subscales were measuring the construct self-efficacy. The revised model consisting of 8 domains was found to fit the data satisfactorily ($\chi^2(810)=942$, $p<0.001$; RMSEA=0.03; CFI=0.93 and WRMR=0.91). The descriptive statistics for each item within each domain post CFA are presented in Table 2.

Internal consistency

The average inter item correlations (r) for each domain ranged from 0.16 to 0.64 with the domains *Knowledge*, *Social Influences*, *Beliefs about Capabilities*, *Beliefs about Consequences*, *Behaviour Regulation* and *Memory, Attention, Decision Processes and Environment* demonstrating adequate levels ($r > 0.15$ and $r < 0.50$) of internal consistency (Table 2).

Discriminant validity

Six domains were found to display discriminant validity according to Fornell and Larcker (1981) suggesting that these domains measure a distinct construct. The scales within the domain *Beliefs about Capabilities* shared variance with the domain *Beliefs about Consequences*.

Discussion

A questionnaire measuring the behavioural determinants of adjuvant hormonal therapy MTB was developed based on the TDF and was tested in a sample of women with stage I-III breast cancer prescribed hormonal therapy. The proposed structure of the TDF was tested using CFA and the questionnaire demonstrated good psychometric properties, with the majority of domains showing good internal consistency reliability and discriminant validity.

This is the first study to develop a measure of the behavioural determinants of hormonal therapy MTB based on the TDF. MTB has been shown to be influenced by multiple determinants including patient related factors and health care provider and health care system related factors (e.g. quality of health care provider-patient communication) (Kardas, Lewek, & Matyjaszczyk, 2013) The application of the TDF enabled the development of a coherent and comprehensive measure of the behavioural determinants of MTB. Existing models of MTB such as social cognition models or self-regulatory models which emphasise the importance of patient beliefs about their illness and treatment and ability to follow treatment advice, are not as comprehensive and do not include automatic processes such as habit formation which determine MTB or consider the broader health care influences. (Jackson, Eliasson, Barber, & Weinman, 2014)

Eight of the 14 domains within the framework were determined relevant to the questionnaire measuring the behavioural determinants of hormonal therapy MTB. However only one domain *Skills* was excluded from the framework. The 8 domains comprised of a combination of domains from the framework e.g. 3 domains (*Intention, Goals, Reinforcement*) were combined into one domain (*Intentions and Goals and Reinforcement*). The adjustments to the framework were made to adequately reflect and account for the relationship between the constructs within the individual domains, which were shown to determine MTB and were based on previous research and the current CFA findings. (Cahir et al., 2014) Huijg et al.,(2014) also found that items measuring the domains *Reinforcement* and *Goals* measured a combination of domains in a generic questionnaire of behavioural determinants and that these domains may not be able to be discriminately measured. They also found that items measuring general feelings (e.g. stress) were able to discriminately assess the domain *Emotion* while emotions relating to performing a specific behaviour (e.g. affect) were not able to. In the current study emotions relating to the behaviour of taking/not taking hormonal therapy were determined to be measured by the domain *Beliefs about Consequences*.

There are a number of limitations to this study which need to be taken into consideration when interpreting the results. The sample size was adequate but given the number of variables measured within each domain a larger sample would provide increased confidence in the reliability and validity of the measure. Women were sampled from one hospital only and the modifications to the TDF need to be evaluated across the general breast cancer population. Further research is also needed to confirm the reliability and validity of the questionnaire. The domains *Beliefs about Capabilities* and *Beliefs about Consequences* did not have adequate discriminant validity. The domain *Beliefs about Consequences* included a larger number of constructs than the other domains and some of these constructs may also be relevant to other domains. Hormonal therapy treatment is associated with a number of side-effects, including arthralgia, hot flashes and gynecologic symptoms which can range in severity.(Guth, Myrick, Schotzau, Kilic, & Schmid, 2011) The domain *Beliefs about Capabilities* did not sufficiently measure women's ability to cope with hormonal therapy side-effects and this measure of capability needs to be included in future studies. The domain *Intentions, Goals and Reinforcement* did not have adequate internal consistency and some items may be highly redundant with each other and need to be re-evaluated and tested.

Hence, although the application of the TDF enables a comprehensive measure of the behavioural determinants of MTB, the number of domains and underlying constructs need to be assessed by a large amount of items and existing scales were not available for some unique aspects of MTB. The selection of constructs within each domain was based on previous research and expert guidance but these constructs may not in fact be highly relevant to hormonal therapy MTB or may not have been effectively measured leading to decreased validity of the measurement of some domains. Equally some constructs which were excluded based on previous research may in fact be relevant. Further work is required to establish which constructs are essential for determining MTB and adequately measure the given domains.

One of limitations of the TDF in its current form is that it is a descriptive framework and it does not specify relationships between domains. (Francis et al., 2012) It is feasible that the lack of discriminant validity for the domains *Beliefs about Consequences* and *Beliefs about Capabilities* is a result of a relationship between the determinants of MTB within these domains. The Health Belief Model has previously been applied as a framework to explain MTB, with beliefs about disease severity, personal susceptibility to recurrence, efficacy of treatment, self-efficacy, barriers to treatment and cues to action suggested as significant

influences on health behaviours and some of these determinants are measured by the domains *Beliefs about Consequences* and *Beliefs about Capabilities*.(DiMatteo, Haskard, & Williams, 2007) Within the TDF the boundaries between the various domains require more clarification and precision. Future research should not only establish the essential constructs for determining MTB, but should also identify and model the appropriate theories that are relevant to hormonal therapy MTB and assess if the identified constructs and domains are related to each other, prior to intervention design.

This study has also not established the criterion validity of the questionnaire on hormonal therapy MTB. Women in the sample were asked to self-report their hormonal therapy MTB and there was some indication of differences across domains for the different MTB groups but the numbers within each group were too small for formal analysis. A larger scale study of women with stage I-III breast cancer prescribed hormonal therapy is currently underway to establish criterion validity and this will also identify the key domains and determinants of hormonal therapy MTB and assess potential relationships between them. This will enable the development of a more refined and effective questionnaire that can be used in clinical practice. Prospective cohort studies are also needed to investigate the predictive validity of the questionnaire and the extent each domain can predict future hormonal therapy MTB.

Notwithstanding the further work required to improve the reliability, validity and generalisability of the questionnaire, a theoretical based measure of the behavioural determinants of hormonal therapy MTB has been developed and can be used as a tool for informing the development of interventions to improve MTB. A recent Cochrane review of MTB interventions concluded that to date only a minority of published interventions have improved MTB or enhanced patient outcomes.(Nieuwlaat et al., 2014) In general, reviews of MTB interventions have reported similar findings; with some intervention components being potentially effective, but small sample sizes and suboptimal methodology often preventing strong conclusions and most studies have been developed without a thorough theoretical understanding of the factors that influence MTB.(van Dulmen et al., 2007) The application of the TDF enables a comprehensive assessment of the determinants of hormonal therapy MTB and it also specifies how to target particular theoretical domains through a number of effective behaviour change techniques (BCTs).(Cane, Richardson, Johnston, Ladha, & Michie, 2015) Previous theories and frameworks used in MTB have identified a range of potential determinants but they have not specified how to change MTB. Theoretically based

tailored interventions using BCTs may be more effective at improving hormonal therapy MTB.

The focus of the current study has been on hormonal therapy MTB in women with stage I-III breast cancer but the measures within this questionnaire may be relevant to MTB in other medical conditions and disease groups. The World Health Organisation has reported that on average 30-50% of patients prescribed medications for chronic illnesses do not adhere to their prescribed medication regimen.(Sabaté, 2003) Patient beliefs and behaviour processes such as habit formation are likely to characterise MTB in all medical conditions and treatments, with some specific determinants of MTB being significant for particular conditions or treatments e.g. HIV and mental illness.(Horne & Weinman, 1999)

Conclusion

This study describes the development and initial validation of a TDF based questionnaire measuring the behavioural determinants of hormonal therapy MTB. Initial results indicate that the measure is reliable and valid and can be used to measure determinants of hormonal therapy MTB in clinical practice. Further research is needed to determine and improve the psychometric properties of the questionnaire and to fully understand its strengths and limitations. In addition, more research is needed to establish if the questionnaire is valid for MTB in other disease groups and in other settings. This will increase knowledge about the factors related to MTB and may help establish which techniques are most effective at addressing each of the components of MTB, resulting in more effective and pragmatic MTB interventions.

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Conflict of interest

The authors declare that they have no conflict of interest

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Endnote

^aThe MIs (>10) were provided by Mplus for all parameters constrained to zero and indicate when an item may cross load or load onto a different factor. The standardised residual matrix items that are either under or over-predicted by the model for which values >+/- 2.58 are considered to be large.(Brown, 2015)

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Appendix I

Domain	Construct	Measurement
Knowledge	Overall knowledge about hormonal therapy	1 question developed from qualitative interviews
	Sources of knowledge/information	1 question developed from qualitative interviews
	Satisfaction with information about hormonal therapy	Satisfaction with information about medicine scale (SIMS)- Action and Usage subscale and Potential problems scale ¹
Social Influences	Support and Barriers	Adherence Determinants Questionnaire Support/Barriers subscale - adapted and reduced to 3 questions ²
	Social norms	Injunctive norms –3 questions adapted from Trinh et al. (2014) analysis of motivational outcomes in breast cancer survivors from the Theory of Planned Behaviour ³
		Descriptive norms –2 questions adapted from Trinh et al. (2014) analysis of motivational outcomes in breast cancer survivors from the Theory of Planned Behaviour ³
Social Identity	Support from oncologist	Patient-Centred Care Items from National Initiative on Cancer Care Quality Breast Cancer Patient Survey- 1 question ⁴
	Support from oncology services - one main point of contact/support	Patient-Centred Care Items from National Initiative on Cancer Care Quality Breast Cancer Patient Survey-1 question ⁴
	Relationship with oncologist- listening	Patient-Centred Care Items from National Initiative on Cancer Care Quality Breast Cancer Patient Survey- 1 question ⁴
	Relationship with oncologist- understanding	Patient-Centred Care Items from National Initiative on Cancer Care Quality Breast Cancer Patient Survey- 1 question ⁴
	Relationship with oncologist- respect	Patient-Centred Care Items from National Initiative on Cancer Care Quality Breast Cancer Patient Survey- 1 question ⁴
	Relationship with oncologist- time	Patient-Centred Care Items from National Initiative on Cancer Care Quality Breast Cancer Patient Survey- 1 question ⁴
Beliefs about Capabilities	Action self-efficacy	3 questions based on the health action process approach (HAPA) ⁵
	Maintenance self-efficacy	3 questions based on the health action process approach (HAPA) ⁵

Domain	Construct	Measurement
	Recovery self-efficacy	3 questions based on the health action process approach (HAPA) ⁵
	Strategies for coping with medication side-effects	The 20-item measure assesses strategies for coping with treatment side effects, and includes scales of Positive Emotion Focused Coping, Social Support Seeking, Nonadherence, Information Seeking, and Taking Side Effect Medications ⁶
Personality (included with Beliefs about Capabilities)	Resilience	Brief Resilience Scale ⁷
Beliefs about Consequences	Perceived severity of breast cancer	Adherence Determinants Questionnaire- Perceived severity of disease subscale ²
	Perceived susceptibility to breast cancer	Adherence Determinants Questionnaire- Perceived susceptibility to disease subscale ²
	Perceived utility of adhering to hormonal therapy	Adherence Determinants Questionnaire- Perceived utility of adhering subscale ²
	Illness perceptions	Brief Illness Perceptions Scale- Consequences subscale- adapted to reference breast cancer recurrence ⁸
	Beliefs about hormonal therapy- necessity and concerns	Beliefs about Medicines Questionnaire (BMQ)- necessity and concerns subscales ⁹
	Outcome expectancies	5 questions developed from qualitative interviews about outcome expectancies in relation to taking or not taking hormonal therapy
		4 questions adapted from Phillips et al.(2013) perceived risk of cancer recurrence in breast cancer survivors (2 questions in relation to taking hormonal therapy and 2 questions in relation to not taking hormonal therapy) ¹⁰
Emotion (included with Beliefs about Consequences)	Concern about breast cancer recurrence	Breast cancer recurrence worry scale ¹¹
Intentions	Intention to take hormonal therapy as prescribed	Adherence Determinants Questionnaire- Intentions to adhere subscale ²
Goals (included with Intentions)	Autonomous motivation	Treatment Self-regulation Questionnaire- 6 questions adapted for hormonal therapy MTB ¹²
	Introjected regulation	Treatment Self-regulation Questionnaire- 2 questions adapted for hormonal therapy MTB ¹²

Domain	Construct	Measurement
	External Regulation	Treatment Self-regulation Questionnaire- 4 questions adapted for hormonal therapy MTB ¹²
	Amotivation	Treatment Self-regulation Questionnaire- 3 questions adapted for hormonal therapy MTB ¹²
	Goal conflict	Adapted Illness Intrusiveness Ratings- Physical Well-Being (2 questions), Work and Finances (2 questions), Marital, Sexual and Family Relations (3 questions), Recreation and Social Relations (3 questions), Other aspects of life (3 questions) ¹³
	Temporal Self-Regulation	Time perspective questionnaire ¹⁴
Reinforcement (included with Intentions and Goals)	Perceived reinforcement and goal conflict and facilitation	4 questions developed from qualitative interviews
Behaviour Regulation	Action planning	4 questions adapted from Sniehotta et al (2005) action planning for long-term lifestyle change ¹⁵
	Coping planning	4 questions adapted from Sniehotta et al (2005) coping planning for long-term lifestyle change ¹⁵
	Action control	Action control- 6 questions- Awareness of standards (2 questions), self-monitoring (2 questions) and self-regulatory efforts (2 questions) ¹⁶
Memory, Attention, Decision Making	Forgetting/difficulties remembering to take hormonal therapy	Morisky adherence scale – first two items (MMAS-4) ¹⁷
	Forgetting/difficulties remembering to get prescription refilled	1 question developed from qualitative interviews
	Forgetting/difficulties recalling medication usage	1 question developed from qualitative interviews
	Habit strength- history of repetition, automaticity (lack of control and awareness, efficiency)	Self-report Behavioural Automaticity Index (SRBAI) ¹⁸
Environmental Context and Resources	Environmental Context- forget when travelling or leaving home	1 question developed from qualitative interviews
	Environmental Context- forget when interruptions to normal routine	1 question developed from qualitative interviews

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Table 1: Self-reported hormonal therapy non-adherence (Voils scale) per MTB group
(N=218)

MTB	N (%)*	Voils Mean (SD)
Adherent and persistent	193 (88.53)	1.55 (0.64)
Non-adherent and persistent	12 (5.50)	2.11 (1.01)
Non-persistent**	13 (5.96)	2.10 (1.64)

* Missing data for 5 women

** Non-persistent women were no longer taking hormonal therapy and reported adherence was in relation to when they were taking hormonal therapy (prior to stopping)

Table 2: Descriptive statistics for the 8 TDF domains (N=223)

Domain	Construct	Measure	Average inter-item correlation
		<i>Median (IQR)</i>	
Knowledge	Action and usage	6 (4, 8)	0.47
	Potential problems	2 (0, 5)	
	General knowledge	3 (2, 3)	
		<i>Median (IQR)</i>	
Social Influences	Support and barriers to MTB	12 (9, 12)	0.18
	Injunctive norms	7 (6, 7)	
	Descriptive norms	7 (5, 7)	
		<i>N (%)</i>	
Social Identity	Support from oncologist (right level)	166 (78)	0.54
	Support from oncology services - one main point of contact/support	156 (70)	
	Relationship with oncologist-listening (yes)	171 (82)	
	Relationship with oncologist-understanding (yes)	166 (80)	
	Relationship with oncologist-respect (yes)	177 (85)	
	Relationship with oncologist- time (yes)	155 (75)	
		<i>Median (IQR)</i>	
Beliefs about Capability	Action self-efficacy	10 (9 ,10)	0.35
	Maintenance self-efficacy	10 (9, 10)	
	Recovery self-efficacy	10 (9, 10)	
	Resilience	4 (3 ,4)	
		<i>Median (IQR)</i>	
Beliefs about Consequences	Perceived severity of breast cancer	9 (8 ,11)	0.16
	Perceived susceptibility to breast cancer	11 (9, 12)	
	Perceived utility of adhering to hormonal therapy	15 (11, 18)	
	Illness perceptions	9 (7, 10)	
	Beliefs about hormonal therapy- necessity	16 (14, 18)	
	Beliefs about hormonal therapy- concerns	12 (10, 15)	
	Outcome expectancies- perceived outcomes if take/don't take hormonal therapy	11 (9, 13)	
	Outcome expectancies- perceived cancer recurrence risk if take hormonal therapy	-0.88 (-1.59, 0.04)	
	Outcome expectancies- perceived cancer recurrence risk if don't take hormonal therapy	0.04 (-0.54, 0.75)	
	Concern about breast cancer recurrence	2 (1 , 2)	
		<i>Median (IQR)</i>	
Intentions, Goals and	Intention to take hormonal therapy as	14 (14, 14)	0.64

Domain	Construct	Measure	Average inter-item correlation	
Reinforcement	prescribed			
	Autonomous motivation	6 (5, 7)		
	Introjected regulation	5 (4, 7)		
	External Regulation	3 (1, 4)		
	Amotivation	3 (2, 4)		
	Adapted Illness Intrusiveness Ratings-Physical Well-Being	2 (0, 3)		
	Adapted Illness Intrusiveness Ratings-Work and finances	1 (0, 4)		
	Adapted Illness Intrusiveness Ratings-Martial, sexual and family relationships	2 (0, 4)		
	Adapted Illness Intrusiveness Ratings-Recreation and social relationships	1 (0, 3)		
	Adapted Illness Intrusiveness Ratings-Other aspects of life	0 (0, 2)		
	Perceived reinforcement and goal conflict and facilitation	2 (2, 3)		
			<i>Median (IQR)</i>	
	Behaviour Regulation	Action planning	3 (3, 4)	0.23
Coping planning		3 (2, 3)		
Action control- awareness of standards		3 (2, 3)		
Action control- self-monitoring		3 (2, 4)		
Action control- self-regulatory effort		3 (3, 4)		
			N (%)	
Memory, Attention, Decision Making and Environment	Forgetting/difficulties remembering to take hormonal therapy (No)	152 (68)	0.27	
	Forgetting/difficulties remembering to get prescription refilled (No)	213 (96)		
	Forgetting/difficulties recalling medication usage (No)	197 (88)		
	Environmental Context- forget when travelling or leaving home (No)	207 (93)		
	Environmental Context- forget when interruptions to normal routine (No)	185 (83)		
			<i>Median (IQR)</i>	
		Habit strength- history of repetition, automaticity (lack of control and awareness, efficiency)	3 (3, 4)	