Predicting adherence to combination antiretroviral therapy for HIV in Tanzania: A test of an

extended Theory of Planned Behaviour model

Abstract

Objectives: Combination antiretroviral therapy (cART) for HIV is widely available in sub-Saharan Africa. Adherence is crucial to successful treatment. This study aimed to apply an extended Theory of Planned Behaviour (TPB) model to predict objectively measured adherence to cART in Tanzania.

Design: Prospective observational study (n=158) where patients completed questionnaires on demographics (Month0), socio-cognitive variables including intentions (Month1), and action planning and self-regulatory processes hypothesised to mediate the intention-behaviour relationship (Month3), to predict adherence (Month5).

Main Outcome Measures: Taking adherence was measured objectively using the Medication Events Monitoring System (MEMS) caps. Model tests were conducted using regression and bootstrap mediation analyses.

Results: Perceived behavioural control (PBC) was positively (β=.767, p<.001, R^2=57,5%) associated with adherence intentions. Intentions only exercised an indirect effect on adherence (B=1.29[0.297 to 3.15]) through self-regulatory processes (B=1.10[0.131 to 2.87]). Self-regulatory processes (β=.234, p=.010, R^2= 14.7%) predicted better adherence.

Conclusion: This observational study using an objective behavioural measure, identified PBC as the main driver of adherence intentions. The effect of intentions on adherence was only indirect through self-regulatory processes, which were the main predictor of objectively assessed adherence.

Key words: adherence; antiretroviral therapy; HIV/AIDS; Theory of Planned Behaviour; Tanzania

Predicting adherence to combination antiretroviral therapy for HIV in Tanzania: A test of an extended Theory of Planned Behaviour model

Over 70% of all people with HIV live in sub-Saharan Africa (SSA), where combination antiretroviral therapy (cART) is now widely available (World Health Organization, 2014). However, on average about 25% of patients on cART in the developing world do not achieve or maintain adequate levels of adherence (Mills, Nachega, Buchan, et al., 2006). Moreover, a large proportion of patients drop out of HIV care (i.e., treatment non-persistence), with only 70% of patients still enrolled after two years (Fox & Rosen, 2010). Previous studies show that non-adherence precedes non-persistence (Vrijens, Vincze, Kristanto, Urquhart, & Burnier, 2008). Poor adherence and persistence to treatment lead to the development of drug resistant mutations of the virus (Gupta et al., 2012; Stevens, Kaye, & Corrah, 2004), progression towards AIDS (Bangsberg et al., 2001) and premature death; but also to an increased risk of onward viral transmission of (resistant) HIV virus (e.g. Wilson, Law, Grulich, Cooper, & Kaldor, 2008). Hence, intervening on non-adherence before the treatment fails or people drop out of care is important from a patient as well as a public health perspective.

A recent systematic review (Bärnighausen et al., 2011) identified 26 adherence-enhancing interventions in SSA evaluated between 2003 and 2010. The evidence for the effectiveness of most interventions was mixed, and those that were shown to be effective typically produced small or short-term effects. For such interventions to be optimally effective, it is important that they adequately apply effective behaviour change methods to target key modifiable behavioural determinants (Bartholomew, Parcel, Kok, Gottlieb, & Fernandez, 2011; de Bruin, Viechtbauer, Hospers, Schaalma, & Kok, 2009; Kok et al., 2015; Peters, de Bruin, & Crutzen, 2015). An examination of the literature on cART adherence in SSA reveals numerous explorative qualitative studies (e.g. Nachega et al.,

2006; Tuller et al., 2009; Watt et al., 2009, 2010) and a number of quantitative survey studies exploring adherence determinants (e.g. Afolabi, Afolabi, Afolabi, Odewale, & Olowookere, 2013; Maqutu, Zewotir, North, Naidoo, & Grobler, 2010). However, few of these quantitative studies – if any - seem to have used established behavioural theory to develop the survey, and to have examined this in a prospective study with an objective measure of adherence. One theory that has been successfully used in a range of behavioural domains (e.g., Cooke, Dahdah, Norman & French, 2016; Sheeran et al., 2016), and also by the authors in previous qualitative and intervention studies on HIV treatment adherence – including in Tanzania - is the Theory of Planned Behaviour (TPB; de Bruin, Hospers, van den Borne, Kok, & Prins, 2005; de Bruin, Hospers, van Breukelen, Kok, Koevoets, & Prins, 2010; de Bruin et al., in press; Lyimo, de Bruin, van den Boogaard, Hospers, van der Ven, & Mushi, 2012).

The Theory of Planned Behaviour

Theory of Planned Behaviour (Ajzen, 1991) is an established model for explaining and predicting health behaviour. Its key premise is the positioning of intention (defined as a plan to carry out a given behaviour) as the proximal predictor of behaviour. Intention, in turn, is predicted by three factors: attitude, subjective norm and perceived behavioural control. Attitude refers to the cognitive and affective evaluation of the behaviour in question. Subjective norm reflects the perceived approval or disapproval of significant others in relation to the behaviour. Perceived behavioural control (PBC) refers to the perception whether or not the behaviour is within one's control, and the perceived ease or difficulty of executing the behaviour.

TPB is one of the main theoretical models used in health psychology and behavioural medicine, and has been found to predict a wide range of behaviours (McEachan, Conner, Taylor, & Lawton, 2011). However, so far only a few studies applied the TPB model to

medication adherence (Holmes, Hughes, & Morrison, 2014) and the results provide mixed support for the theory. Only one study examined the usefulness of TPB for predicting medication adherence in a Sub-Saharan African country (South Africa; Saal & Kagee, 2012). Among South-African patients, PBC – but none of the other variables - explained 12% of variance in intentions to adhere to cART, but TPB constructs did not explain a significant amount of variance in self-reported adherence. The authors pointed out the limitations of using a self-report outcome measure, but also suggested that TPB may not be applicable for predicting adherence to cART in this context. A prospective observational study with an objective measure of adherence could yield more conclusive evidence on the usefulness of the TPB model for predicting medication adherence in a low resource environment.

Adding additional variables to the parsimonious TPB model in an attempt to explain more variance in behaviour is quite often done in health psychology research (e.g. Ajzen, 2011; Ajzen & Sheikh, 2013, 2016; Conner & Armitage, 1998). These additional variables, often derived from other theories, can increase the proportion of variance explained by the model and contribute to a better understanding of the behaviours in question. One such variable is the motivational construct of anticipated regret (from regret theory; e.g. Loomes & Sugden, 1982), which has been demonstrated to relate strongly to intentions and health behaviours (including medication adherence), and explain behaviour over and above of TPB variables (Brewer, DeFrank, & Gilkey, 2016; Fraenkel, McGraw, Wongcharatrawee, & Garcia-Tsao, 2005; Sandberg & Conner, 2008). Another category of variables are those hypothesised to help bridge the so-called intention-behaviour gap (Sheeran, 2002), inspired by Control Theory (Carver & Scheier 1998). In particular, the constructs action planning (Sniehotta, Scholz, & Schwarzer, 2005) and self-regulatory processes (de Bruin et al., 2012; also referred to as action control by Sniehotta et al., 2005) such as monitoring goal progress

and responding to discrepancies between performance and goals set, have been found to explain the relationships between intentions and health behaviours. Hence, in the present study we explored whether the TPB variables, complemented by constructs from Regret and Control Theory, to predict HIV treatment adherence behaviour.

The Present Study

The objective of this observational study is to examine an extended TPB model in predicting adherence to cART, measured objectively with the Medication Event Monitoring System (MEMS-caps, electronic pill caps that register date and time of pill bottle opening), among HIV-infected patients receiving cART in Tanzania. We have previously demonstrated that MEMS-cap use is feasible in this setting (Lyimo et al., 2011).

Method

Participants and procedure

Participants were 158 clients of two rural HIV clinics in the Kilimanjaro region in northern Tanzania, where HIV treatment is given according to national guidelines free of charge. Eligible participants had to be over 18 years old, on cART for at least 6 months, regular clients in one of the clinics (meaning that they attended this clinic and not several different clinics for their treatment), and not being treated for tuberculosis (see also Lyimo et al., 2013). Participants were paid 5000 Tanzanian Shilling (approximately US $3) to cover the cost of lunch or transport. The study was approved by the Tanzania National Institute for Medical Research (NIMR; reference number: NIMR/HQ/R.8a/Vol.IX/812).

Participants attended the clinics monthly for their routine appointments. The study involved four face-to-face interviews conducted by one of five trained research assistants using a pre-tested, structured questionnaire. We used interviewers rather than self-completion of questionnaires because some of the patients were illiterate. All participants provided informed consent. At enrolment (Month 0), participants completed the first

interview, where they provided information on background and demographic factors. At that point, participants were also given a Medication Events Monitoring System (MEMS) cap (Aardex Ltd.), an electronic pill bottle that registers date and time of pill bottle opening, and were shown how to use it. Patients were following a variety of medication regimes and, in some cases, were taking a combination of several different drugs. If patients were using multiple antiretrovirals, the drug that was used most frequently was placed in the MEMS-bottle. Ninety-eight percent of patients were taking their medication twice a day (the exception were patients on Atripla, which was taken only once a day). Nearly 75% of patients were taking two tablets a day, but some regimens included up to 7 tablets. MEMS data were downloaded monthly during each clinic visit by the clinic data clerk without the patient being present.

At Month 1, participants were interviewed for the second time, now providing information on motivational factors (TPB variables, anticipated regret). At Month 3, participants were interviewed again and data were collected on intention-behaviour mediators (i.e. self-regulatory processes and action planning). At Month 5, patients handed in the MEMS-cap. The different constructs were assessed at different time points because, first, there were too many items to assess in one questionnaire. Second, reports on the intention-behaviour mediators should concern the period over which patients formulated their intentions (i.e., the future), hence we judged it most appropriate to assess these constructs at a separate time point.

Measures

All questionnaires were translated into Kiswahili based on agreement between two bilingual members of the project team. In order to ensure comprehensibility of the items and response categories, each of the questionnaires were pre-tested (think-aloud interviews) among 8 to13 patients who were did not participate in the full study (the number of people

who contributed to pre-testing varied between questionnaires, as we continued with pre-testing each questionnaire until no further issues were identified). Following the pre-testing, translation mistakes were corrected, wording of the unclear questions was changed, and the questionnaire was shortened so that its administration would take no more than 30 minutes. All measures used in the study are listed in the Appendix.

Psychometric properties of the measures used are summarised in Table 1. Internal consistency reliability of the various scales was examined with Cronbach's alpha and Mokken scaling analysis (Gillespie, Tenvergert, & Kingma, 1987). Following this, several items were removed from scales so that all scales used in the analysis were homogeneous. H is the coefficient of scale homogeneity calculated in Mokken scaling and when this is above .30 the scale is homogenous and the items can be combined in a single score (Mokken, 1971). All final scales used in the analyses had satisfactory to excellent internal consistency reliability ($\alpha > .50$) and homogeneity ($H > .45$).

Motivational factors and intention.

Attitude. Attitude was measured using six items presented as 5-point semantic differential scales adapted from Fishbein & Ajzen (2010; e.g. 'Taking all my ARVs every day is: Very unimportant – very important'). An average attitude score was computed from responses to the six items.

Subjective norm. Pilot work had revealed that patients in this population often only reveal their seropositive status to only one or two important others (i.e., it is a private behaviour), and some have told nobody about their HIV status or cART use. Therefore, for the measurement of subjective norm, participants were asked to identify one or two important people (e.g., partner, sister, brother, mother) who knew that the participant was HIV positive and was taking HIV medication. For each identified person, participants were requested to respond to the item: '[Person] thinks that I should always take all my ARVs

every day, regardless of challenging situations I may encounter' on a scale from 'strongly disagree' (1) to 'strongly agree' (5). Many participants reported having disclosed their HIV status to only one person or group: their response to the single item was then used as a measure of this construct. If participants reported two sources of subjective norm, their responses to the two items were averaged.

Perceived behavioural control (PBC). PBC was measured using 11 items. Three items were adapted from Fishbein & Ajzen (2010) (e.g. 'Always taking all my ARVs every day is totally up to me'), and participants responded to each on a scale from (1) 'strongly disagree' to (5) 'strongly agree'. The other eight items were adapted from a previous study in Tanzania (Watt, 2007; e.g. 'How confident are you that you will be able to take your ARVs even if you would have side effects'?). Participants responded on a scale from (1) 'not confident at all' to (5) 'very confident'. Responses to the 11 items were averaged to form a single PBC score.

Anticipated regret. Two items (adapted from Sandberg & Conner, 2008) were used to measure anticipated regret. Both items started with 'If I would miss a dose of ARVs, I would feel…' and participants responded on a scale from (1) 'absolutely no regret' to (5) 'very much regret' for item 1, and from 'absolutely not upset' to 'very much upset' for item 2.

Intention. The intention to take ARVs as prescribed was measured using three items ('I intend/expect/will try very hard to always take all my ARVs every day, regardless of challenging situations I may encounter'; adapted from Fishbein & Ajzen, 2010). Participants responded on a scale from (1) 'strongly disagree' to (5) 'strongly agree'. An intention score was created by averaging responses to the three items.

Intention-behaviour mediators.

Self-regulatory processes. Nine items were used to measure self-regulatory processes (e.g. 'I closely monitor whether I take all my ARVs every day'), with responses given on a scale from 'never' (1) to 'always' (5). Three of the items were adapted from de Bruin et al (2012), while the other six were developed following interviews in the community (Lyimo, de Bruin, van den Boogaard, Hospers, van der Ven, & Mushi, 2012). However, psychometric analyses indicated that the 9-item scale was not unidimensional and that a more internally consistent and efficient subscale of four items could be created, focussed specifically on the planning and monitoring of medication intake. The 4-item scale was used in all subsequent analyses.

Action planning. Four items adapted from Luszczynska and Schwarzer (2003) were used to measure action planning regarding taking medication over the next eight weeks (e.g. 'Looking at the next eight weeks, I know exactly for each day how often I will take my medicine'). Participants responded on a scale ranging from 'strongly disagree' (1) to 'strongly agree' (5).

Outcome.

Objective measure of adherence. MEMS caps were used to objectively assess adherence (i.e., execution or implementation of the regimen; Blaschke, Osterberg, Vrijens, & Urquhart, 2012). Taking adherence over Month 5 of the study ((number of doses taken/number of days) * 100%) was used as the dependent variable in this study.

Analyses plan

A correlation analysis was run to examine bivariate associations. As subjective norm had a high proportion of missing data because 13% of patients reported not having told any important others about their HIV and cART use, models were first run without this variable, and then full models with subjective norm included were run for comparison. Demographic variables were controlled for in the models if they were significantly ($p < .05$) correlated

with the outcomes of interest. In order to identify psychological variables associated with the intention to adhere to medication, intention was regressed on attitude, PBC, and anticipated regret. In order to identify significant predictors of adherent behaviour, adherence in month 5 was regressed on (Step 1) demographic variables; (Step 2) attitude, perceived behavioural control, anticipated regret; (Step 3) adherence intention; and (Step 4) self-regulation skills and action planning. Bootstrapping was used to explore the role of action planning and self-regulation in mediating the relationship between intentions to adhere and adherence behaviour.

Results

One-hundred and fifty-eight patients were included in the study and filled out the initial questionnaire. Demographic characteristics are presented in Table 2. Due to incomplete data, three cases were removed from the analyses of predictors of intention. A further five cases were removed from the analyses of adherence, as these patients were lost to follow-up and did not provide questionnaire and adherence data beyond Month 1.

Bivariate associations between the key constructs, intention to adhere and taking adherence are reported in Table 3. Intention to adhere was significantly correlated with perceived behavioural control, subjective norm and anticipated regret. Adherence behaviour was significantly correlated with self-regulatory processes.

Predicting adherence intentions

Demographic variables were not significantly correlated with intentions (all ps > .05). Of the psychological variables, only perceived behavioural control (β = .767, p < .001) was significantly associated with intention. The model accounted for 57.5% of variance in the intention to take medication as prescribed (F(3, 151) = 68.00, p < .001;). A model including subjective norm was run for comparison (n = 133), explaining 55.1% of variance in

intention ($F(4, 129) = 39.63$, $p < .001$). Subjective norm was not a significant predictor ($\beta = .035$, $p = .610$) and the pattern of associations remained the same.

Predicting adherence

Adherence was regressed on demographics (Step 1), attitude, perceived behavioural control, anticipated regret (Step 2), intention (Step 3), action planning and self-regulatory processes (Step 4, see Table 5). At Step 1, being married was significantly associated with better adherence ($\beta = .177$, $p = .030$), while age and gender were not ($ps > .05$). At Steps 2 and 3, only marital status remained a significant predictor of adherence (all other $ps > .05$). At Step 4, self-regulatory processes predicted adherence ($\beta = .234$, $p = .010$), marital status remained significant ($\beta = .163$, $p = .044$), and the full model explained 14.7% of variance in adherence ($F(9, 140) = 2.69$, $p = .006$).

The model was also ran using logistic regression (adherence <95% versus ≥95%) given the skewed distribution of adherence, and the same results were obtained (results not shown). We also ran a model including subjective norm (n = 129), which predicted adherence in Step 2 ($\beta = .293$, $p = .004$), and in Step 3 ($\beta = .292$, $p = .004$) and Step 4 ($\beta = .299$, $p = .002$), resulting in the association between marital status and adherence becoming non-significant ($ps > .010$ in Steps 2-4). However, after deleting one influential case (Cook's distance > 0.80), the association between subjective norm and adherence became non-significant ($ps > .10$ in Steps 2-4).

Indirect effect of intention on behaviour

Preacher and Hayes' (2008) bootstrapping was used to investigate whether intention may have had an effect on behaviour through self-regulation and/or action planning (de Bruin et al., 2012; Sniehotta et al., 2005). Even if an independent variable (intention) does not predict the dependent (adherence) directly, the independent variable can still have an indirect effect on the dependent (Hayes, 2009; Rucker, Preacher, Tormala, & Petty, 2011).

In a model with 5000 bootstrapping samples (and controlling for marital status), the direct effect of intention was not significant (as above) (B = -1.62 [-4.31 to 1.07]). The overall indirect effect of intention on adherence was significant (B = 1.29 [0.297 to 3.15]) with a significant mediation by self-regulatory processes (B = 1.10 [0.131; 2.87]). Action planning did not mediate the intention-behaviour relation (B = 0.195 [-0.073; 1.06]). See Figure 1 for the full mediation model.

Discussion

The present study was designed to identify predictors of adherence to cART in Tanzania, and by extension test the applicability of an extended TPB model to explain cART adherence behaviour in a low resource setting. In the univariate analyses, anticipated regret, subjective norm, and PBC were associated with intentions; the latter association was so strong (r = .78) that in the regression analysis only PBC remained predictive. The intention to adhere was not found to be directly associated with adherence. In fact, only self-regulatory processes (and subjective norm, but this seemed to rely on one influential case) predicted adherence. Intentions were found to exercise an indirect effect on adherence through self-regulatory processes. Hence, this observational study, using a well-validated objective adherence measure, identified PBC as the main driver of adherence intentions, and self-regulatory processes as main predictor of adherence.

A recent meta-analysis (Rich, Brandes, Mullan, & Hagger, 2015) reported that, in studies of chronic illness, the average proportion of variance in intention to adhere explained by TPB variables was 32.9%. Studies focusing specifically on adherence to medication consistently report a strong association between perceived behavioural control and intentions to adhere (e.g., Abraham, Clift, & Grabowski, 1999; Saal & Kagee, 2012), with up to 70% of variance in intention explained by PBC alone (Abraham et al., 1999). In this study, PBC accounted for nearly 60% of variance in adherence intentions. As a whole,

however, the extended TPB model did not perform as expected: only self-regulatory processes predicted adherence directly, while attitude, anticipated regret, perceived behavioural control, and action planning did not; and intention only showed an indirect effect. Overall, 14.7% of the variance in adherence was explained. A previous meta-analysis by Rich et al. (2015) found that, across 27 studies, attitude, subjective norm (operating indirectly via their effect on intention), and perceived behavioural control (operating both directly and indirectly via intention) predicted adherence, albeit weakly (explaining only 9% of variance). That the current results are less supportive of these constructs being predictive of adherence behaviour may be due to the majority of the studies in the meta-analysis being conducted in high-resource settings and using self-report measures of both the predictors and adherence (common method variance).

The finding that intention had only an indirect effect on adherence behaviour, speaks to the wider literature on the intention-behaviour gap (Sheeran, 2002; Sheeran et al., 2016) and the ongoing debate about the usefulness of TPB as a theory of health behaviour and health behaviour change (Sniehotta et al., 2014). As intentions and adherence scores were both quite high, missed or delayed doses may have occurred largely due to non-intentional causes, such as simply forgetting or a lack of access to medication (e.g. while travelling or that the patient could not visit the clinic on time for a refill; Mills, Nachega, Bangsberg, et al., 2006). Also, as participants in this study had already been on cART for 6 months or longer, they may have established a routine where taking medication became a habitual behaviour, which may have led to a weaker effect of intention and other volitional variables on adherence.

The indirect effect of intention on adherence was mediated by self-regulation processes, indicating that participants who had a stronger intention to adhere were also more likely to monitor their medication intake, plan to pick up a new dose of medication before

they ran out, or reflect on the reasons for missed doses in order to maintain good adherence in the future. These self-regulatory processes were the main predictor of adherence in this study. Self-regulatory processes were examined once previously by de Bruin et al. (2012) in the context of adherence to HIV medication (Study 1) and physical exercise (Study 2) in a high income setting, and were also found to mediate the intention behaviour relation. That self-regulatory processes not only mediate intentions across behaviours but also across different cultures and resourced settings, confirms that this may be a key construct to consider when studying how people translate their intentions into behaviour.

Strengths & limitations

A particular strength of this study was the low dropout, so that almost all patients (95%) were included in the main analyses. Additionally, the measurement of the predictors of intention and the intention to adhere in Month 1, then measuring the mediators in Month 3 and adherence itself in Month 5 allowed for making predictive statements about the relationship between psychological variables, the mediators, and adherence. Finally, the availability of objectively assessed behavioural data over a whole month avoids the issues with common method variance and strongly suggest that the data is valid and reliable.

The study may suffer from several limitations. First, using interviewers may have introduced bias in responses based on interviewer style. Second, some scales did not perform very well, so that items had to be removed from scales or subscales had to be created. Third, the monitoring of adherence with MEMS may have resulted in higher levels of adherence, although this effect is assumed to dissipate after several weeks (Cook, Schmiege, McClean, Aagaard, & Kahook, 2012). Also, the observed range of psychological predictors and objectively measured adherence was quite restricted, potentially due to a ceiling effect. This may have contributed to the low proportion of variance in adherence behaviour explained by the model. Finally, the analysis did not control for the fact that

patients in this study used different regimens, reflecting prescribing in routine care, which is influenced by how well medication is tolerated, previous viral resistance, and medication availability. These regimen were prescribed for once or twice daily. Although regimen complexity can impact on adherence (Nachega et al., 2014), all these regimen were fairly simple so there is little reason to assume the determinants of non-adherence would vary across these regimen.

Conclusion

This study revealed that perceived behavioural control predicts adherence intentions, but the primary finding relates to the importance of self-regulatory processes in managing adherence to cART in a low-resource setting (corroborating similar findings in a high-resource setting, e.g., de Bruin et al., 2012). Another key finding is that the extended TPB model did not perform well in this observational study with an objective behavioural outcome measure, which begs the question whether this theory or the research methods (e.g.., surveys with interviewers) are fully appropriate for identifying cART adherence predictors in this context.

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Table 1. Scale Properties of Measures Used in the Study.

	H	α
Anticipated regret	0.532	0.517
Attitude	0.451	0.714
Perceived behavioural control	0.583	0.905
Self-regulatory processes (4-item scale)	0.513	0.670
Action Planning	0.754	0.916
Intention	0.786	0.885

Note : an H of 0.50 indicates a strong scale, 0.40 a medium and 0.30 a weak scale (Mokken, 1971).

Table 2. Demographic Characteristics of the Sample (n = 158).

	%	Mean	SD
Age		43.75	10.25
Gender: female	69.6		
Treatment regimen			
Triomune30	68.0		
Combivir + Efavirenz	18.3		
Combivir + Nevirapine	10.4		
Combivir + Abacavir	0.7		
Atripla	2.0		
Abacavir + Didamosine + Lupnavir	0.7		
Viral load at Month 1			
Undetectable	57.0		
Detectable	39.9		
Missing data	3.1		
Religion			
Christian	94.9		
Muslim	5.1		
Marital status			
Married	38.6		
Separated or divorced	12.0		
Widow/widower	36.7		
Single	12.7		
Education			
No education/some primary education	15.2		

Completed primary school/some secondary education	74.1
Completed secondary school	8.8
Post-secondary/vocational education	1.9

Table 3. Spearman's Rank Correlations between Study Variables (n = 150).

|	Attitude	Perceived behavioural control	Subjective norm	Anticipated regret	Intention	Action planning	Self-regulatory processes	Adherence at Month 5
ATT	1							
Perceived behavioural control	.118	1						
Subjective norm (n = 130)	.294***	.437***	1					
Anticipated regret	.267**	.243**	.007	1				
Intention	.049	.779***	.373***	.206**	1			
Action planning	.173*	.143	.049	.278**	.135	1		
Self-regulatory processes	.072	.214**	.175*	.217*	.287***	.477***	1	
Adherence at Month 5	.092	-.073	.082	.028	-.070	.115	.189*	1
Mean (SD)	4.68 (0.32)	4.56 (0.42)	4.78 (0.43)	4.67 (0.46)	4.58 (0.46)	4.43 (0.59)	4.80 (0.34)	96.87 (7.66)
Median (IQ range)	4.67 (0.50)	4.54 (0.84)	5.00 (0.13)	5.00 (0.50)	4.67 (1.00)	4.50 (1.00)	5.00 (0.33)	100.00 (1.86)

Note: * p < .05; ** p < .01; *** p < .001.

Table 5. Regression of Adherence on TPB Variables, Action Planning and Self-regulatory Processes.

Variable	B Step 1	B Step 2	B Step 3	B Step 4
Step 1				
Age	.081	.103	.105	.061
Gender	-.162	-.150	-.149	-.144
Marital status	.177*	.179*	.175*	.163*
Step 2				
Attitude		.122	.123	.108
Perceived behavioural control		-.050	-.075	-.077
Anticipated regret		-.030	-.029	-.088
Step 3				
Intention			.032	-.034
Step 4				
Action planning				.107
Self-regulation				.234**
R^2	.057	.071	.072	.147
ΔR^2	.057*	.014	.001	.075***

Note: * $p < .05$, ** $p = .01$, *** $p < .01$.

Figure 1. Extended TPB model to predict adherence intentions and behaviour.
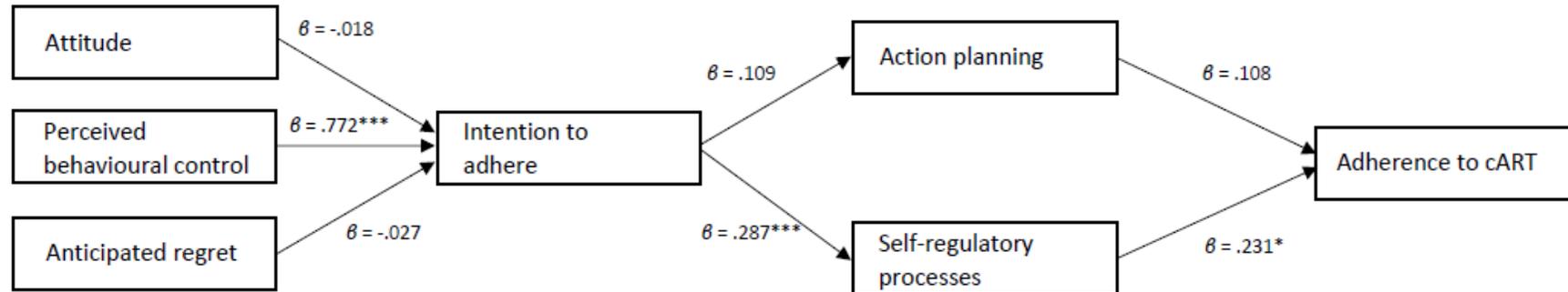
Note: Statistics reported next to the arrows are standardised regression coefficients. Marital status was controlled for in all analyses. * *p* < .05, *** *p* < .001.

Appendix- All items included in the paper

Attitude

Taking all my ARVs every day is:
        Very unimportant – very important
        Very unwise – very wise
        Very useless – very useful
Taking all my ARVs every day would make me feel:
        Very bad – very good
        Very disgusting – very enjoyable
        Very unpleasant – very pleasant

Subjective norm

Person/group 1 thinks that I should always take all my ARVs every day, regardless of challenging situations I may encounter *(strongly disagree – strongly agree)*
Person/group 2 thinks that I should always take all my ARVs every day, regardless of challenging situations I may encounter *(strongly disagree – strongly agree)*

PBC

Always taking all my ARVs every day is totally up to me *(strongly disagree – strongly agree)*
If I want to, I am confident that I can always take all my ARVs every day regardless of the situation *(strongly disagree – strongly agree)*
I feel completely in control over my ARV intake *(strongly disagree – strongly agree)*
Imagine that you are in the following situations, how confident are you that you will be able to take your ARVs, even if:
You would have side effects? *(not confident at all – very confident)*
You would travel away from home for a day? *(not confident at all – very confident)*
You would be very busy (e.g. working, community events, activities in church or mosque)? *(not confident at all – very confident)*
You would become sick? *(not confident at all – very confident)*
You would be feeling very tired physically? *(not confident at all – very confident)*
You would be with someone when you have to take your medications who doesn't know that you are HIV positive? *(not confident at all – very confident)*
You would have a lack of food? *(not confident at all – very confident)*
You would have consumed alcohol (e.g. after having had an offer for alcohol)? *(not confident at all – very confident)*

Anticipated regret

If I would miss a dose of ARVs, I would feel:
        Absolutely no regret – very much regret
        Absolutely not upset – very much upset

Intention

I intend to always take all my ARVs every day, regardless of challenging situations I may encounter *(strongly disagree – strongly agree)*
I will try very hard to always take all my ARVs every day, regardless of challenging situations I may encounter *(strongly disagree – strongly agree)*
I expect to always take all my ARVs every day, regardless of challenging situations I may encounter *(strongly disagree – strongly agree)*

Self-regulatory processes (final four items used in the analyses)

I closely monitor whether I take all my ARVs every day *(never – always)*
I make sure that I get new ARVs at the clinic before my ARVs are finished *(never – always)*
If I notice that I have not taken my ARVs or I have taken them too late, I think about what the reason for that was and how I can prevent that from happening again *(never – always)*
I watch carefully that I take all my ARVs every day *(never – always)*

Action planning

Looking at the next 8 weeks, I know exactly for each day how often I will take my medicine *(strongly disagree – strongly agree)*
Looking at the next 8 weeks, I know exactly for each day at what time I will take my medicine *(strongly disagree – strongly agree)*
Looking at the next 8 weeks, I know exactly for each day where I will take my medicine *(strongly disagree – strongly agree)*
Looking at the next 8 weeks, I know exactly for each day how (i.e. with or without food and fluid) I will take my medicine *(strongly disagree – strongly agree)*

Note: All items were presented with 5-point response scales, with the anchors presented here in italics.