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A randomized controlled trial to test the effectiveness of planning strategies to improve medication adherence in patients with cardiovascular disease

Background: Low levels of adherence to medication prescribed to treat and manage chronic disease may lead to maladaptive health outcomes. Theory-based, easy-to-administer interventions that promote patients' effective self-regulation of their medication-taking behaviour are needed if adherence is to be maximised. We tested the effectiveness of an intervention adopting planning techniques to promote medication adherence. **Methods:** Outpatients with cardiovascular disease (N=71) were allocated to either an experimental condition, in which participants were asked to form implementation intentions and coping plans related to their treatment, or to a no-planning control condition, in which participants received no treatment. Patients also completed self-report measures of medication adherence, self-efficacy, and beliefs in medication necessity and concerns. Measures were administered at baseline and at 6-week follow-up. **Results:** Results revealed no overall main effect for the intervention on medication adherence. Post hoc moderator analyses revealed that the intervention was effective in patients with lower necessity beliefs compared to those with higher necessity beliefs. **Conclusion:** While current findings have promise in demonstrating the conditional effects of planning interventions, there is a need to replicate these findings by

manipulating planning and beliefs independently and testing their direct and interactive effects on medication adherence.

Keywords: Medication adherence, implementation intention, coping planning, cardiovascular disease, behaviour change intervention

Introduction

Health outcomes in chronic disease are highly dependent on treatment adherence (DiMatteo, Giordani, Lepper, & Croghan, 2002). Research has demonstrated that medication adherence in non-institutionalized patients with chronic diseases has been estimated at only 50% (DiMatteo, 2004). In the context of cardiovascular disease (CVD), which causes 17.3 million deaths every year worldwide (WHO, 2011), medication adherence is essential to minimise illness progression and poor medication adherence problems increases the risk of mortality and the number of subsequent hospitalizations (Ho et al., 2008).

Interventions that increase the capacity of outpatients with chronic disease to effectively manage their treatment, that is, to better *self-regulate* their medication-taking behaviour, are needed (O'Brien et al., 2015; Wallace, Brown, & Hilton, 2014). Health professionals have turned to behavioural scientists and social psychologists to provide an evidence base for interventions based on psychological theory that are effective in promoting better self-regulation of health behaviour. Prominent among these theories are theories of motivation that identify individuals' intentions as a key predictor of behaviour (Heckhausen & Gollwitzer, 1987; Schwarzer, 1992). However, research has demonstrated that a large population of individuals has strong intentions to engage in health behaviour but fail to do so (Sheeran, 2002). These 'inclined abstainers' (Orbell & Sheeran, 1998) or 'unsuccessful intenders' (Rhodes & de Bruijn, 2013) have difficulty in converting their good intentions into actual behaviour. Furnishing intentions with plans, known as implementation intentions, to enact those intentions has been shown to be an effective strategy in improving relations between intentions and behaviour (Gollwitzer & Sheeran, 2006). Self-regulation strategies like implementation intentions may help in countering the gap between intention to take medication and actual medication adherence. Implementation intentions are a mental act linking an anticipated critical situation or cue and an effective goal-directed response (Gollwitzer, 1993). The plans are

hypothesized to affect better enactment of intended behaviour by assisting recall of the intended behaviour and facilitating efficient enactment of the behaviour on presentation of the cue. Recent meta-analyses have demonstrated that implementation intentions are effective in improving behavioural adherence to health-related behaviours like physical activity (Bélanger-Gravel, Godin, & Amireault, 2013), healthy diet (Adriaanse, Vinkers, De Ridder, Hox, & De Wit, 2011), and attendance to screening programmes (Cooke & French, 2008).

Numerous studies have demonstrated that implementation intentions are effective in promoting adherence to medication in epileptic (Brown, Sheeran, & Reuber, 2009), coronary artery disease (Lourenco et al., 2014), and hypertensive (O'Carroll, Chambers, Dennis, Sudlow, & Johnston, 2014) patients. In contrast, another study (Jackson et al., 2006) did not find any effect of implementation intentions in improving adherence to antibiotic medication. However, one factor that might have mitigated the effectiveness of the intervention in Jackson et al.'s study (2006) was that they did not adopt an 'if-then' format for their implementation intention. The 'if-then' clearly designates the link between the cue encountered in the situation and the behaviour (e.g., "If situation x arises, then I will do behavior y (Gollwitzer & Sheeran, 2006), and is strongly advocated in implementation intention research (Chapman, Armitage, & Norman, 2009; Hagger & Luszczynska, 2014).

Alongside implementation intentions, coping planning is another behavioural planning technique that has been developed to overcome barriers to anticipate situations that may prevent individuals from engaging in the desired behaviour (Schwarzer, 2008; Sniehotta, Schwarzer, Scholz, & Schüz, 2005). Forming a coping plan helps individuals arrive at novel ways to manage health behaviour by heightening situational and response cues for the new, desired behaviour and assist in replacing cues to the habitual, unintended behaviour. In the context of taking CVD medication, salient barriers are mostly related to treatment and vary among patients as a function of disease type and severity. Generally, patients are prescribed

antianginals, statins, anticoagulants, or antiplatelet drugs. Thus, the barriers usually relate to the iatrogenic (e.g., liver disease, kidney failure, diabetes) and side (e.g., memory lapses) effects related to the patients' medication especially statins and antianginal drugs. Randomised controlled trials have shown efficacy of the combination of action planning with barrier management, a strategy closely linked with coping planning, in promoting medication adherence in patients with coronary heart disease (Lourenco et al., 2014).

Recent conceptual reviews on the effectiveness of planning interventions in health research indicated the importance of testing for potential moderators of planning effects (Hagger & Luszczynska, 2014; Hagger et al., 2016). Behavioural and self-efficacy beliefs have been proposed as candidate moderators. Focusing on behavioural beliefs, there is research indicating that attitudes regarding the target behaviour, or accompanying conditions or illnesses, may determine whether or not implementation intentions will be effective. For example, Brown et al. (2009) demonstrated that forming an implementation intention resulted better medication adherence among epileptic patients with low concerns about their condition but not among those with high concerns. Although concerns about illness do not directly equate to concerns about medication, this research illustrates how beliefs about the condition which have strong relevance to the behavior in question, that is, medication adherence, have the potential to affect the efficacy of plans. Brown et al.'s (2009) findings are consistent with research that has suggested that planning interventions are effective for individuals with self-regulatory problems (e.g. Brandstätter, Lengfelder, & Gollwitzer, 2001; Webb & Sheeran, 2004). The likely mechanism behind the moderating effects of such beliefs is that individuals with low concerns may not be sufficiently attentive to key cues to enact and may, therefore, suffer from regulatory problems and benefit more from planning strategies that promote better attention to salient cues and more automatic links between the cue and action.

Another potential moderator of planning intervention effectiveness is self-efficacy (Schwarzer, 1992). Research has demonstrated that enhancing self-efficacy increases the effectiveness of an implementation intention intervention on health behaviour (Kellar & Abraham, 2005). Given the strong links between self-efficacy and motivation and intentions to engage in health behaviours, this work is consistent with the contention that implementation intentions are effective for individuals that are motivated to engage in the behaviour. Consistent with the model of action phases (Heckhausen & Gollwitzer, 1987), motivation is a prerequisite for volitional strategies like planning to have an effect, therefore, it would be expected that self-efficacy beliefs, which are closely aligned with motivation, will moderate the effectiveness of plans on behaviour. Thus, beliefs regarding the illness and behaviour, and self-efficacy, may determine whether implementation intentions are effective (Wray, Waters, Radley-Smith, & Sensky, 2006). Accounting for the effects of these moderators is important as the main effect of implementation intentions in the absence of such beliefs or self-efficacy may be null and, therefore, mask the true nature of the effect of planning interventions on behaviour.

The Present Study

Given research that has shown the effectiveness of both implementation intentions and coping planning in promoting adherence in health-related behaviours, the aim of the present study was to examine the effectiveness of a combined intervention adopting both techniques in promoting medication adherence in patients with CVD. Specifically, the study adopted a 2 (intervention condition: control group vs. implementation intention and coping planning group) x 2 (time: baseline (T1) vs. post-intervention follow-up (T2)) randomized controlled design with medication adherence measured at T1 and follow-up post-intervention measures collected at T2, 6 weeks later. We expected the research to make an original contribution to the literature by testing the effectiveness of a theory-based planning intervention which combined two types of planning based on psychological theory on a behaviour and will have important

ramifications for practice in managing illness in CVD patients. We also expected the findings to have the potential to extrapolate in other settings where the promotion of medication adherence is important and compliance is sub-optimal. In terms of specific hypotheses, we expected that participants from the intervention group would exhibit higher medication adherence scores, measured on two self-report measures of medication adherence, the Morisky Medication Adherence Scale and the Visual Analogue Scale, at T2 while controlling for medication adherence at T1, compared to the control group. We also included additional measures of intentions, medication beliefs, and self-efficacy. These variables may be important when it comes to identifying the potential mechanisms for the effects of the planning interventions. For example, the effects of implementation intentions are not expected to result in changes in intentions, only behaviour, because such planning interventions are proposed to act in a 'post-decisional' manner (Heckhausen & Gollwitzer, 1987). However, intention strength , beliefs such as beliefs about illness (Wray et al., 2006), and Bandura's self-efficacy construct, defined as individuals perceived personal capacity to engage in a given behaviour (Kellar & Abraham, 2005), have been proposed as possible moderators of planning interventions. We have included these measures to enable us to conduct exploratory post hoc tests of these constructs as moderators of the planning intervention on behaviour.

Method

Participants and procedure

The present study adopted a randomised controlled design. We estimated our sample size at 54 participants minimum (Gollwitzer & Sheeran, 2006; power = .80, alpha = .05, d = .59) for a 2 x 2 ANOVA (Faul, Erdfelder, Lang, & Buchner, 2007). Patients were recruited from a hospital outpatient cardiac rehabilitation clinic. The clinic provided rehabilitation programs for patients with different types of CVD after treatment for serious cardiac events

(e.g. myocardial infarction, heart failure, heart surgery). Patients attended the clinic for six weeks, which represented the follow-up duration, for between two and three half-days per week, depending on the patient's condition. During the half-day treatment sessions in the clinic, patients participated in prescribed exercise sessions supervised a physiotherapist (exercise bicycle, light gymnastics). Patients had attended regular appointments with the consultant in charge of their care throughout their clinic attendance, including one immediately before they arrived at the cardiac rehabilitation center and one before they left, to draw up a complete report on their program of care. All the patients participated in patient education sessions on tobacco consumption, stress and cardiovascular disease.

Patients were eligible to participate in the current study if they were older than 18 years, had had a recent major cardiac event, and had been referred to the clinic for the first time. Participants were mostly men (80.3%) with an average age of 59.54 (*SD* = 11.31) years (see Table 1), 78.9% were married, 25.4% had completed primary, secondary or high school education, and 74.6% completed post-school vocational training or attended university. Most patients were prescribed statins to reduce cholesterol levels, vasodilators or Beta blockers to manage angina pectoris symptoms, or anticoagulants or antiplatelet drugs to prevent myocardial infarction.

Data collection at Time 1 (T1) took place when patients arrived for their first session at the clinic and data collection at Time 2 (T2) took place when patients completed their final session six-weeks later. Participants did not receive any remuneration for the study. At T1, patients were told that the study was about "medication intake in patients with cardiovascular disease". Eligible patients (N = 71) were randomly allocated to the implementation intention and coping planning group or control group using a random numbers table generated by the experimenter (Figure 1). No allocation concealment was made regarding the sequence generation. No patient declined to participate in the study. Patients were blinded to group

allocation, but the experimenter administering the study materials was not. Patients were asked to complete the paper and pencil questionnaires individually in a quiet room. If the questionnaire was unclear for the patients, the experimenter was on hand to answer questions. At T1, patients in both groups completed study baseline measures including current self-reported medication adherence, socio-demographic data, and scales measuring self-efficacy and beliefs about medicines, which took approximately 10 minutes to complete. Patients allocated to the implementation intention plus coping planning group were then required to engage in the exercises that contained the implementation intention and coping planning manipulations, which took 10 additional minutes to complete. At T2, patients in both groups completed follow-up study measures identical to those administered at T1. Patients were debriefed and thanked for their participation. Data were collected from May to December 2014 and we stopped the trial when we had collected data from sufficient numbers of participants in the study to achieve adequate statistical power.

Informed consent and anonymity

Prior to data collection, patients read a study information sheet, which they were able to take home with them, and signed an informed consent form. The information sheet provided details of the study, expectations of participation, and participants' rights, benefits, and potential risks of participation. We detached the informed consent from the questionnaire in order to maintain participant anonymity. At T1 and T2, participants formed a unique identifier comprising the first two letters of their mother's name, father's name, and their month and date of birth. This was used instead of names to match participants' data across T1 and T2. Ethical approval for the study was obtained from the institutional review board of the CERNI (Comite d'Ethiques pour les Recherches Non Interventionnelles, Pôle Grenoble Cognition, France) prior to data collection.

Measures

The 8-item Morisky Medication Adherence Scale (MMAS-8). Medication adherence was measured using the French version of the MMAS-8 (Korb-Savoldelli et al., 2012), including eight items with scores ranging from 0 to 8. Higher scores represented better adherence. We used the MMAS-8 score in three ways: the total score, the unintentional non-adherence score and the intentional non-adherence score (Toll, McKee, Martin, Jatlow, & O'Malley, 2007). Items referring to the forgetting to take medication comprised the unintentional non-adherence scale (e.g. "Do you sometimes forget to take your medication?"). Items referring to barriers to medication adherence made up the unintentional medication non-adherence scale (e.g. "When you feel like your treatment is under control, do you sometimes stop taking your medicine?"). Participants responded on a binary scale with "yes" (1) or "no" (0) anchors for seven of the items with one item reverse scored and on a 5-point Likert scale for one item ("never or rarely" (1), "from time to time" (0.75), "sometimes" (0.50), "frequently" (0.25), "all the time" (0)). Scores on these subscales ranged between 0 and 3, with higher scores representing better adherence.

Visual Analogue scale (VAS) for medication adherence. The single-item visual analogue rating scale (VAS) was used to measure medication adherence. We choose to add an additional measure of medication adherence because the VAS has been shown to be strongly correlated with objective measures of medication adherence (Kalichman et al., 2009). We modified the scale to refer to medication adherence in general: "On a scale from 0 to 100 (0 means that you never take your treatment, and 100 that you always take it, at the prescribed hour and dose), place a cross where you estimate you are."

Beliefs about Medicines Questionnaire (BMQ). Beliefs about medication were measured using five items from the French version of the BMQ (Fall, Gauchet, Izaute, Horne, & Chakroun, 2014). We used the five-item version because it has demonstrated good psychometric properties and reduces response burden on participants (Mann, Ponieman,

Leventhal, & Halm, 2009). Three items were related to the concerns about treatment scale (BMQ-C; e.g. “Having to take medicines worries me”) and two items were linked with the perception of the treatment as a necessity scale (BMQ-N; e.g. “Without my medicines I would be very ill”). Responses were given on a five-point Likert scale (from 1, “strongly disagree”, to 5, “strongly disagree”).

Self-efficacy scale. Finally, a single item was used to measure perceived self-efficacy concerning treatment (Mann et al., 2009): “How confident are you in your ability to take your treatment as the doctor prescribes it?” We chose this validated single-item of self-efficacy to reduce response burden on participants given the considerable number of outcome measures. Participants specified their level of agreement on a five-point Likert scale (from 1, “strongly disagree”, to 5, “strongly disagree”).

Socio-demographic data and disease information. Participants completed a brief socio-demographic questionnaire at baseline including type of CVD, date of diagnosis and initiation of treatment, associated disease(s), help with the management of the treatment (if the patient was given help with their treatment by a relative or a caregiver), use of an organization tool like a pillbox, and treatment history.

Intervention

Implementation intention and coping planning intervention. Manipulations of implementation intention and coping planning components of the intervention were delivered via a printed pen-and-paper exercise. Participants in the implementation intention and coping planning group were first prompted to form implementation intentions by identifying the appropriate place and time to take their medication, and an action they did every day that served as a prompt or cue to take their medication. Similarly to Brown et al. (2009), participants

specified plans for the morning, the afternoon, and evening (e.g., "If it is 8 a.m., and I am in the bathroom, and I have finished brushing my teeth, then I will take my morning medication.")

Participants were then prompted to form coping plans to anticipate and deal with potential barriers. Our method was similar to Armitage's (2008) Volitional Help Sheet. An expert committee identified salient barriers relevant to cardiac rehabilitation context and these were reformulated to an 'if-then' format (Chapman et al., 2009; Lehmann et al., 2014); e.g., "If I am out of my medicines on a Sunday morning, then I will identify a 24h pharmacy from the shop window of my usual pharmacy and take my medication as usual during the day.") Participants were asked to tick the barriers they had encountered, and prompted to formulate their own 'if-then' plans. Salient barriers identified by the patients included memory problems caused by the statins (e.g., "If I have problems with my memory, then…"), the number of medications used to manage iatrogenic effects (e.g., "If I have difficulties managing all the medicines I have, then…"), and the side effects caused by the statins and the antianginals ("If the side effects of my treatment have an impact of my daily routine, then…").

Control group. Participants in the control group only completed the informed consent, medication adherence self-report measures, BMQ and self-efficacy measures, socio-demographic data, and information about the disease and the treatment.

Data analysis

Missing values were replaced using multiple imputation based on estimates obtained from maximum likelihood regression analysis. To avoid type 1 error due to multiple comparisons for the correlations, we adjusted the critical alpha-value using a Bonferroni correction. As there were six comparisons in our analysis, the critical alpha-value was set at .008 (.05/6 = .008) for statistical significance, which means that none of the correlations was statistically significant according to this stringent criterion. We explored the potential for medication beliefs and self-efficacy to moderate the effects of the intervention on behavior by

running a series of moderated multiple regression analyses. In the analyses the main effect of the intervention as a dichotomous dummy-coded variable was included alongside interaction terms reflecting the effect of the intervention conditional on the two sets of beliefs.

Results

Preliminary analyses

Fifteen participants (11 in the implementation intention and coping planning group and four in the control group, namely 21.13% of the initial sample) dropped out of the study prior to the six-week follow-up because they failed to attend the clinic and could not be subsequently contacted.

Attrition checks

Participants who completed the study did not differ significantly from the participants who dropped out with respect to socio-demographic data, disease type and status, type of treatment, and the outcome variables (*p*s > .05; Table 1). However, participants from the experimental group were more likely to dropout than participants in the control group ($p = .04$).

Randomisation checks

Randomisation tests revealed that the intervention group and control group did not significantly differ on gender (χ^2 (1, N = 71) = 1.57, $p = .211$, $\eta^2_p = -.149$), age ($t(69) = -0.85$, $p = .396$, $d = 0.202$), number of medicines ($t(69) = 0.58$, $p = .563$, $d = 0.14$), unit doses per day ($t(69) = 0.63$, $p = .534$, $d = 0.15$), medication adherence measured with the MMAS-8 ($t(69) = 1.60$, $p = .114$, $d = 0.38$) and the VAS ($t(69) = 0.98$, $p = .333$, $d = 0.23$), BMQ-C ($t(69) = -0.89$, $p = .375$, $d = 0.21$) and BMQ-N ($t(69) = 0.43$, $p = .673$, $d = 0.10$) scores, and self-efficacy ($t(69) = 0.85$, $p = .400$, $d = 0.20$) measured at T1, meaning that randomisation was successful.

Table 1 near here

Descriptive statistics and correlations among study variables

Descriptive statistics including means, standard deviations, and Cronbach alpha internal consistency statistics, and zero-order intercorrelations among study variables are presented in Table 2. Cronbach alpha coefficients were satisfactory for the BMQ-N, BMQ-C, and self-efficacy scales. However, coefficients for the scale MMAS-8 scale fell below suggested cutoff values (.70), and indicated problematic internal consistency for the scale. Problems with the internal consistency of the scale have been reported elsewhere, particularly in translated versions of the scale (Al-Qazaz et al., 2010; de Oliveira-Filho, Morisky, Neves, Costa, & de Lyra, 2014) including the French version used here (Korb-Savoldelli et al., 2012). We calculated zero-order correlations between MMAS-8 (total score, intentional non-adherence score, unintentional non-adherence score) and VAS at T2, self-efficacy, BMQ-N and BMQ-C at T1 and planning intervention (a dichotomous dummy-coded variable with -1 assigned to the control group and +1 to the intervention group; see Table 2).

Table 2 near here

Intervention effects[1]

We tested the effects of the implementation intention and coping planning intervention on medication adherence using a multivariate ANOVA with condition (intervention group vs. control group) as the independent variable and MMAS-8 at T2 and VAS at T2 as dependent variables, controlling for medication adherence measures from T1 (MMAS-8 and VAS scores).

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[1]We also tested the effects of the implementation intention and coping planning intervention on medication adherence using a multivariate ANOVA with condition (intervention group vs. control group) as the independent variable and difference scores between MMAS-8 at T2 and T1 and VAS at T2 and at T1 as dependent variables, which did not change the pattern of results. Based on the estimated marginal means, the mean difference at T2 between the control group and the intervention group was -.16 for the MMAS-8 (95% CI, -.65-.32; $\eta^2_p =$ .007) and 2.28 for the VAS measure of medication adherence (95% CI, -2.88-7.44; $\eta^2_p =$ .011).

Means and standard deviations for medication adherence measured at T2 are presented in Table 3. Based on the estimated marginal means, the mean difference at T2 between the control group and the intervention group was -.24 for the MMAS-8 (95% CI, -.73-.25; $\eta^2_{p} = .014$) and 2.21 for the VAS measure of medication adherence (95% CI, -3.04-7.45; $\eta^2_{p} = .010$).

Table 3 near here

Post hoc Tests for Moderators

Given the null effects for the main effect of the intervention, we proceeded to conduct post hoc follow-up analyses in order to gain insight into why our intervention failed to support our predictions. We measured a number of covariates such as age, gender number of diseases suffered by participants, number of medications taken by participants and duration of treatment. However, none of those covariates was associated with medication adherence. For this reason these covariates were not included in the analysis. The regression analyses were conducted on each independent variable separately. As before, because conducting multiple analyses increases type I error rates, we set the alpha level of our statistical tests to $p < .017$ for maximum stringency and to control for type I error rates. This new alpha level was estimated by dividing the conventional alpha level ($p < .05$) by the number of statistical tests conducted (n = 3: a MANOVA plus two regression analyses). In all regression analyses, we obtained bias-corrected confidence intervals by replicating the analysis 10,000 times using a bootsrapping re-sampling method.

The first regression analysis examined the effects of the planning intervention as a dichotomous, dummy coded variable on medication adherence measured by the MMAS-8 at T2 with the necessity (BMQ-N) and concerns (BMQ-C) dimensions of the beliefs in medicines questionnaire as moderators. In the first step of the analysis, the main effects of the intervention group and standardized BMQ-C and BMQ-N scores at T1 were entered into the regression

equation with medication adherence at T1 included as a covariate. This was followed by second and third steps in which interaction terms represented by the product of the intervention group variable with BMQ-N and BMQ-C scores at T1, respectively, were entered into the equation. Results of the analysis are provided in Table 4. The equation in the first step was statistically significant and accounted for 33% of the variance in MMAS-8 scores. In this step the only significant predictor was MMAS-8 scores at T1 with no main effect for the intervention condition or the beliefs variables consistent with the ANOVA results. The addition of the interaction term for planning intervention and BMQ-C scores at T1 in step 2 did not result in a statistically significant step change in the prediction of MMAS-8 scores at T2 or interaction effect and accounted for less than 1% change in variance explained in MMAS-8 scores at T2. The equation in step 3 revealed a statistically significant step change in the prediction of MMAS-8 scores at T2 which accounted for an additional 9% of the variance of MMAS-8 scores. In this step there were statistically significant effects for MMAS-8 scores at T1 and the interaction term comprising intervention condition and BMQ-N scores at T2. The Durbin-Watson test revealed independence of the error terms with a value of 1.75.

To probe the interaction effect found in step 3 of the analysis, we conducted a follow-up simple slopes analysis for the effect of the planning intervention on MMAS-8 scores at T2 for one standard deviation above and below the mean for BMQ-N at T1. Simple slopes analysis showed that the planning intervention resulted in better medication adherence when patients' BMQ-N scores at T1 were lower (β = .49, SE = .17, $t(70)$ = 2.82.73, p = .006) than when BMQ-N scores at T1 were higher (β = -.28, SE = .17, $t(70)$ = -1.75, p = .085).

Figure 2 near here

The second analysis examined the effects of the planning intervention on medication adherence with self-efficacy as a moderator. Medication adherence at T1, intervention group

and standardized self-efficacy scores were entered as main effects in step 1 of the regression equation. An interaction term represented by the product of the intervention group variable with self-efficacy scores at T1 was entered into the equation in step 2. Consistent with the previous analysis, the first model resulted in a statistically significant equation ($F(3, 67) = 11.71$, $p < .001$) and, again, MMAS-8 score at T1 was the only statistically significant predictor ($\beta = .56$, $SE = .13$, $t(70) = 5.53$, $p < .001$). Entering the interaction term in step 2 did not result in a statistically significant increment in variance explained (F_{change} (1, 66) = 2.13, $p = .149$) or a significant interaction effect ($\beta = .48$, $SE = .10$, $t(70) = 1.46$, $p = .149$).

Table 4 near here

Discussion

The aim of the current study was to examine the effectiveness of an intervention combining implementation intention and coping planning in improving medication adherence among patients with CVD. Findings revealed no statistically significant effect of the intervention condition on medication adherence. We also conducted post hoc analyses examining the effect of two candidate moderators of the planning intervention, namely, beliefs about medicines and self-efficacy, on medication adherence. Analyses of the interaction effects revealed that patients with lower beliefs in the necessity of medication exhibited higher self-reported medication adherence scores as a result of the planning intervention, a finding which was contrary to expectations. We found no other interaction effects.

The null fundings for our planning intervention is contrary to the weight of the evidence that has tended to support effects of planning interventions on health behavior, including the relatively few studies that have applied these effect on medication adherence (Brown et al., 2009; Farmer et al., 2012; Jackson et al., 2006; Liu & Park, 2004; Lourenco et al., 2014; O'Carroll et al., 2014; Pakpour et al., 2015). That said, there is research which has found null

effects for implementation intentions and other planning interventions (Jackson et al., 2005; Jackson et al., 2006; Jessop, Sparks, Buckland, Harris, & Churchill, 2014; Scholz, Ochsner, & Luszczynska, 2013; Skar, Sniehotta, Molloy, Prestwich, & Araujo-Soares, 2011). Reconciling these conflicting effects presents considerable challenges to researchers attempting to identify the true effect of planning interventions in health behaviour. Solutions have been sought though an examination of the quality of the studies and other methodological issues including statistical power and sample representativeness. The current research was sufficiently powered to find relatively large effects for the planning interventions, although, of course, the effect size was, according to the current evidence, much smaller than predicted rendering the study underpowered. However, given the effect size reported in the current study, it seems that an extremely large sample would have been needed to detect a statistically significant effect. This suggests that the effect size may be a trivial one and indicates that planning interventions have no practical significance in terms of promoting medication adherence. Of course, a single null finding does not render the effects of planning interventions redundant, but along with other null findings, it does warrant closer scrutiny to explain the effect. Inevitably, the search for such explanations focus on the conditions that magnify or diminish planning intervention effects, that is, what moderator variables are in operation. In the current study, we were able to conduct post hoc analyses examining the potential for medication beliefs and self-efficacy to moderate the effects of the planning intervention. While these analyses were not planned a priori and should, as a consequence, be treated with caution, they at least provide some initial indication of potential moderators.

Focusing on our post hoc moderator analyses, we assumed that patients who perceived their treatment as a necessity would have higher intentions to take their medication consistent with the motivational phase of Heckhausen and Gollwitzer's (1987) model and would be more likely to enact their intention when provided with a plan to do so. We found the opposite pattern

of results. As we controlled for the baseline medication adherence at T1, this cannot be attributed to a ceiling effect in the intervention group. Furthermore, it is noteworthy that the mean necessity belief scores in the implementation intention group were quite high (M = 7.71 out of a maximum possible score of 10) so even low scores on this dimension were not excessively low and were above the mid-point on the scale. One possible explanation could be that the patients who had very high necessity beliefs about their treatment may have already initiated other strategies to take their medication before the intervention. In contrast, receiving the planning intervention may have led to patients with comparatively lower medication necessity beliefs to enact their behaviour in a more automated fashion by the implementation intention exercise (Brandstätter et al., 2001; Sheeran, Webb, & Gollwitzer, 2005; Webb & Sheeran, 2004).

The interactive effects of planning interventions and beliefs on medication adherence in the current study may mirror some of the findings for motivation and planning found in previous studies. There is no clear consensus on the necessity of high motivation to promote behavioural engagement in the presence of planning and there are quite few studies that have shown that low or moderate levels of motivation lead to stronger effects for planning, especially implementation intentions. For example, some authors (Chatzisarantis, Hagger, & Wang, 2010) showed that when people form implementation intentions, intrinsic motivation does not have to be high to promote behavioural engagement. Moreover, Brandstätter et al. (2001; Study 2) showed the efficacy of an implementation intention to initiate goal-directed behaviour in patients with schizophrenia, i.e. people who had fluctuations in action control. Finally, as implementation intention may lead individuals to initiate the behaviour automatically without any conscious input (Brandstätter et al., 2001; Sheeran et al., 2005; Webb & Sheeran, 2004), we could assume that the motivational component does not play an important role in its

enactment. Thus, planning interventions can be effective at modest levels of motivation and may help people who are less committed to the behaviour.

Limitations and Future Directions

While the current study may provide some preliminary data to inform research and practice on potential moderating effects of planning interventions, it is important to note some important limitations and their implications. Most prominent among these, is the relatively low statistical power of the current study. The inclusion of measures of candidate moderators alongside the intervention may have increased the risk of type 1 error. Furthermore, our a priori estimation of sample size did not include calculations for the effects of covariates, multiple outcomes, and moderators, which will have decreased the statistical power of the study. It is important to recognise that research examining the potential moderating effects of social cognitive and belief-based factors in planning interventions has been relatively sparse, and the few studies that have been conducted on this topic are also limited in scope and design (Hagger & Luszczynska, 2014). For example, trials that have tested the direct and moderator effects of planning interventions on health behaviour have tended to be on relatively small samples, recruited at convenience or from homogenous groups, and they have, as a consequence, tended to be underpowered (e.g. Arbour & Ginis, 2004; Brawley, Arbour-Nicitopoulos, & Martin Ginis, 2013; Latimer, Ginis, & Arbour, 2006; Murray, Rodgers, & Fraser, 2009). The sparseness of the research and the limitations of the current study and those that have been conducted previously presents considerable problems in identifying the true effects of moderators of planning interventions on health behaviour. These issues should serve as a catalyst for future high-quality research testing the moderators of implementation intentions on health behaviour. For example, larger sample sizes and a focus on fewer measures would increase the power of the findings and permit more reliable data from which to draw conclusions. Future research should, therefore, consider replicating the current findings but

adopt design features to ensure that tests are fit-for-purpose including testing for moderation using experimental manipulations of moderator variables rather than merely measuring moderators and examining conditional effects, powering a priori for the moderator effects, and conducting the tests in a similar or identical illness context used in the current study. Researchers should also focus on sound conceptual and theoretical propositions to develop hypotheses regarding the mechanisms that underpin moderator effects.

Another limitation of the current study is that we did not use a control group on which we controlled for the degree of information processing that the participants engaged in relative to the experimental group. Research using these kinds of interventions typically present an alternative neutral task to participants in order to control for any reactivity effects due to information processing or load e.g. the 'mere fact' of writing. This may be an important consideration for future research designs. A final limitation was our use of a self-report measure of medication adherence. Even though the MMAS-8 has demonstrated good psychometric integrity in initial development with strong correlations with objective measures of medication adherence (Morisky, Green, & Levine, 1986), problems have been reported with its internal consistency in translated versions. This was also the case in the French translation in the current study with the internal consistency falling below cutoff values in previous research (Korb-Savoldelli et al., 2012) as well as the current study. Correlations of the MMAS-8 with our other measure of medication adherence, the VAS, were significant but modest. Results should, therefore, be interpreted in the context of problems with the reliability of the scales. Furthermore, as with all self-report behavioural measures, the possibility of reporting bias is a real one and a potential source of error variance in our behavioural measure. Future studies should measure medication adherence using objective behavioural measures like electronic pill-monitoring bottles (Park, Howie-Esquivel, & Dracup, 2015).

Conclusion

We expected the current study to make an original contribution to the promotion of better medication adherence in patients with CVD using two theory-based psychological planning techniques and adopting a randomized controlled design. However, we found no main effect of the planning intervention combining implementation intentions and coping planning on medication adherence. Nevertheless, we did find that the planning intervention increased medication adherence among patients who did not have high beliefs in medication necessity before the intervention, which was unexpected and opens up new perspectives on the importance of beliefs in moderating the effects of planning interventions. Our findings highlight the importance of considering belief-based moderators of the effectiveness of planning interventions and without its inclusion we may have concluded that there was no effect of the planning intervention. Results also raise the question as to whether a specific profile of patients, namely those with low, but not zero, beliefs in medication necessity, benefit from the planning intervention. Testing the effect of moderators like beliefs or motives is likely to have increased importance as researchers try to identify the conditions in which planning interventions are most effective in facilitating participation in health behaviour and try to resolve some of the inconsistencies in the observed effects of these interventions on health behaviour.

Supplemental files

Consort statement, Tidier checklists, questionnaires administered to the participants and the SPSS datafiles are available as supplemental files.

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Table 1. Self-reported sample characteristics at baseline (N = 71).

Variable	Control group	Intervention group
Age in years[a]	60.67 (12.67)	58.37 (10.38)
Gender[b]		
Women	5 (13.9%)	9 (25.7%)
Men	31 (86.1%)	26 (74.3%)
Disease[b]		
Myocardial infarction, stent, ACS	33 (91.7%)	28 (80%)
Heart failure, cardiomyopathy	2 (5.6%)	6 (17.1%)
Aortic valve replacement, mitral valve repair	1 (2.8%)	1 (2.9%)
Number of medicines[a]	6.44 (2.25)	6.83 (3.25)
Unit doses per day[a]	7.08 (2.72)	7.63 (4.45)
Medication adherence[a]		
MMAS-8	7.08 (1.04)	7.43 (0.75)
MMAS-8 Intentional non-adherence	2.81 (0.40)	2.91 (0.28)
MMAS-8 Non-intentional non-adherence	2.58 (0.58)	2.66 (0.59)
VAS	91.61 (7.68)	93.27 (6.61)

Note. [a]Values in parentheses are standard deviations; [b]Values in parentheses are proprotion of the overall sample with the characteristic. ACS = Acute coronary syndrome; Unit doses per day = number of doses of medication taken per day; MMAS-8 = Morisky Medication Adherence Scale (8 items); VAS = Visual Analogue Scale for Medication Adherence.

Table 2. Descriptive Statistics, Cronbach Alpha Reliability Coefficients, and Zero Order Correlation Coefficients Among Study Variables.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14
1. MMAS-8 T1	1													
2. MMAS-8 T2	.578**	1												
3. VAS T1	.325**	.262*	1											
4. VAS T2	.214	.262*	.439***	1										
5. BMQ-C T1	.030	.052	-.124	-.006	1									
6. BMQ-C T2	.010	-.070	-.052	-.045	.690***	1								
7. BMQ-N T1	.051	.197	-.015	-.030	.074	.163	1							
8. BMQ-N T2	.002	.156	-.010	-.075	.064	.223	.723***	1						
9. SE T1	.070	.051	.132	.152	-.405***	-.313	.003**	-.062	1					
10. SE T2	-.045	.205	.030	.102	-.350**	-.372**	.210	.105	.443***	1				
11. Age	.039	-.031	.065	-.072	-.200	-.075	-.071	-.009	.078	.172	1			
12. N. medicines	.045	.170	.112	.134	-.083	.014	.117	.197	-.024	.040	.059	1		
13. Unit doses/day	.042	.142	.095	.131	-.072	.016	.113	.204	-.027	.008	.104	.959***	1	

14. Group[a]	.189	.210	.117	-.026	-.107	-.207	.051	.166	.101	.201	-.102	.070	.075	1
α	.33	.59	–	–	.74.	.79	.74	.88	–	–	–	–	–	–
Mean	7.07	92.43	91.42	8.44	7.79	7.59	7.81	3.82	4.03	59.54	6.63	7.35	–	–
SD	1.22	7.17	11.92	3.52	3.68	2.39	2.51	1.23	1.13	11.31	2.78	3.66	–	–

Note. [a]Dummy coded variable representing the intervention condition with participants allocated to the implementation intention and coping planning intervention coded as +1 and participants allocated to the control condition coded as -1. MMAS-8 = Morisky Medication Adherence Scale (8 items); VAS = Visual Analogue Scale for Medication Adherence; BMQ-C = Beliefs in Medicines Questionnaire, “Concerns” dimension; BMQ-N = Beliefs in Medicines Questionnaire, “Necessity” dimension at T1; SE: = Self-Efficacy.

Table 3. Estimated marginal means for the medication Adherence Scores for the Intervention and Control Groups at T2 (6-week follow-up).

Outcome measures at T2	Intervention group				Effect size		
	Control (n = 36)		Intervention[a] (n = 35)		Mean Difference	95% CI	
	M	SD	*M*	SD			
MMAS-8	6.95	0.17	7.19	0.17	-0.24	-0.73	0.25
VAS	92.50	1.83	90.30	1.85	2.21	-3.04	7.45

Note. [a]Implementation intention and coping planning intervention. T1 = Time 1; T2 = Time 2; MMAS-8 = 8-item Morisky Medication Adherence Scale; VAS = Visual analogue scale for medication adherence; CI = Confidence Interval.

Table 4. Prediction of Medication Adherence at T2.

Step and predictor	β	95% CI		R^2_{adj}	ΔF
		LB	UB		
Step 1[a]:					
MMAS-8 T1	.67*	.39	.88		
Group	.12	-.11	.34	.33	9.77*
BMQ-N T1	.08	-.05	.22		
BMQ-C T1	.01	-.05	.08		
Step 2[b]:					
MMAS-8 T1	.69*	.44	.89		
Group	.12	-.11	.33		
BMQ-N T1	.08	-.05	.20	.34	1.23
BMQ-C T1	.02	-.04	.08		
Group x BMQ-C T1	-.14	-.44	.13		
Step 3[c]:					
MMAS-8 T1					
Group	.67*	.40	.88		
BMQ-N T1	.12	-.09	.31		
BMQ-C T1	.07	-.05	.17	.42	10.75*
Group x BMQ-C	.01	-.05	.06		
T1	-.11	-.35	.14		
Group x BMQ-N T1	-.37	-.65	-.04		

Note. MMAS-8 = Morisky Medication Adherence Scale; BMQ-C = Beliefs in Medicines Questionnaire, "Concerns" dimension; BMQ-N = Beliefs in Medicines Questionnaire, "Necessity" dimension. β = Standardized beta coefficient; CI = Biased-corrected confidence interval of the standardized beta; R^2_{adj} = Adjusted squared multiple correlation that indicates variance explained in the dependent variable; ΔF = incremental F-value for the regression model.

$^{*}p < .05$ $^{**}p < .01$ $^{***}p < .001$