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Can a Multifaceted Intervention Including Motivational InterviewingImproveMedication Adherence, Quality of Life and MortalityRates in Older Patients Undergoing Coronary Artery Bypass Surgery? A Multicenter Randomized Controlled Trialwith 18-month Follow-up

Short title/running head: Effects of a multifaceted intervention on medication adherence and mortality rates in older CABG patients

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Compliance with Ethical Standards

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Conflicts of Interest

Chung-Ying Lin, Mehdi Yaseri, Amir H. Pakpour, Dan Malm, Anders Broström, BengtFridlund, Andrea Burri and Thomas L. Webb declare that they have no conflicts of interest relevant to the content of this manuscript.

Key points

- A multifaceted intervention including psycho-education, motivational interviewing, andshort message services improved medication adherence among patients aged over 65 who were undergoing coronary artery bypass graft (CABG) surgery.
- The effects of the multifaceted intervention on medication adherence were maintained eighteen months following the intervention.
- Quality of life and survival rates improved as a consequence of increasing medication adherence.

Abstract

*Background.*Patients undergoing coronary artery bypass graft (CABG) surgery are required to take a complex regimen of medications for extended periods, and they may have negative outcomes because they struggle to adhere to this regimen. Designing effective interventions to promote medication adherence in this patient group is therefore important.

*Objective.*The present study aimed toevaluate the long-term effects of a multifaceted intervention(psycho-education, motivational interviewing, and short message services) on medication adherence, quality of life (QoL), and mortality ratesin older patients undergoing CABG surgery.

*Methods.*Patients aged over 65 years from 12 centers were assigned to theintervention (EXP; n=144) or treatment as usual (TAU; n=144)groups using cluster randomization at center level.Medication adherence was evaluated using Medication Adherence Rating Scale (MARS), pharmacy refill rate, and lipid profile;QoL using Short-Form36. Data were collectedat baseline;three, six, and eighteen months after intervention.Survival status was followed up at eighteen months.Multi-level regressionsand survival analyses for hazard ratio (HR) were used for analyses.

*Results.*Compared to patientswho received TAU, theMARS, pharmacy refill rate, and lipid profile of patients in the EXP group improved six months after surgery (p<0.01)andremained so eighteen months after surgery (p<0.01). QoLalso increased among patients in the EXPgroup as compared to those who received TAU at eighteen-month post-surgery(physical component summary score p = 0.02; mental component summary score p = 0.04). HR in the EXP group compared to the TAU group was 0.38 (p=0.04).

*Conclusion.*The findings suggest that a multifaceted intervention can improve medication adherence in older patients undergoing CABGsurgery, with theseimprovements being maintained aftereighteen months. QoL and survival rates increased as a function ofbetter medication adherence.

ClinicalTrials.gov NCT02109523

1. Introduction

Coronary artery bypass graft (CABG) surgeryis often considered to be the primary intervention forindividuals suffering from severe coronary artery disease and has been shown to increase quality of life (QoL) and life expectancy [1-3].The mortality rate during CABG surgery has declined [4-8], including among older patients,even up to 90 years or above [6,7].However, although CABG is a promising surgery for older patients with severe coronary artery disease, there are some reasons to suspect thatolder patients may have more negative outcomes after CABG surgery than younger patients[9,10].

Patients undergoing CABG surgery are required to take a complex regimen of medications over a long period of time [9].Therefore, one reason why older patients may have more negative outcomes is that they struggle to adhere to this regimen [10].Some characteristics ofthe geriatric population, including hearing difficulties,impaired cognition, poormanual dexterity and vision, and low tolerance ofthe effects of drugs mayresult in low rates of adherence [11]. In addition, older patients undergoing CABGsurgery share some of the factors that lead to noncompliance among younger patients, such as poor education about the importance, and adverse effects of, each medication, polypharmacy (the use of four or more medications), the need to take multiple doses each day, the cost of medication, and the incorrect use of medication [12]. Because medication adherence positively influences outcomes(e.g., decreases functional disability, morbidity, and mortality) [13,14], it is important to design interventions that can improve medication adherence among older patients undergoing CABG surgery.

A meta-analysisof33 randomized controlled trials of interventions designed to improve medication adherence among older patients [15] found that the interventions incorporating psycho-education, behavioral interventions, and interventions based on the theory of planned

behavior significantly improved medication adherence (effect size, *d*=0.33) and knowledge about medications (*d*=0.48) relative to control conditions. However, the meta-analysisdefined older patients in a relatively broad way (i.e., as those older than 60 years). Hence, their results may not generalize to older populations (i.e., those aged over 65 years); especially as age has been found to influence medication adherence among people with myocardial infarction [13]. Also, none of the primary studies focused on promoting medication adherence amongolder patients undergoing CABGsurgery; therefore, more evidence is needed on interventions that can improve medication adherence for olderpatients undergoing CABG surgery.

Multifaceted interventionsseem to be an appropriate way to promote medication adherence because many factors can simultaneouslyinfluence the behavior [16,17]. For example, a prospective study found that medication counseling accompanied by planningincreased medication adherence amongpatients with a mean age of 59 years undergoing CABGsurgery [18]. However, given that older samples (e.g., those aged over 65)may have additional issues that prevent them from successfully adhering to medications (e.g., further impairments to hearing and cognition);it is possible that additional intervention components are needed to promote medication adherence among these patients. Therefore, the present research developed an intervention that consisted of psycho-education, motivational interviewing (MI) [19-21] accompanied by planning, and sending reminders via a short message service (SMS)[22] in an effort to increase medication adherence amongpatients aged over 65 undergoing CABG surgery. The intervention alsoencouraged the patients' family to help because family members may influence medication adherence amongpatients undergoing CABG surgery [23], especially in Eastern cultureswhere family relationships are particularly valued [24].

In addition to identifying effective ways to promote medication adherence, it is also important to understand how and why interventions are effective – i.e., to identify the underlying mechanisms. Multifaceted interventions likely change relevant cognitions and self-regulatory processes that, in turn, lead to changes in the outcomes of interest (namely, medication adherence). Based on extant research, it seems likely that patients' intentions, behavioral automaticity, levels of action and coping planning, perceived behavioral control, self-monitoring, beliefs about medicines, and illness perceptions could all potentially mediate the effects of the intervention on outcomes (i.e., medication adherence, QoL, and mortality rate). Intentions reflect the direction and strength of a person's motivation to perform the relevant behavior (such as medication adherence in our study) [18]. Behavioral automaticity reflects whether a patient engages in a behavior (e.g., taking medication) relatively automatically; that is quickly, easily, and without the need for conscious thought[25]. Action and coping planning reflect the extent to which patients haveidentified obstacles that may prevent them from engaging in a behavior and made plans specifying how they plan to deal with these;perceived behavioral control reflects how competent someone feels in their ability to perform a behavior [26]. Self-monitoring indicates whether someone regularly reflects on and monitors his/her behavior and/or the outcomes of their behavior [27,28]. Beliefs about medicines refer to a patient's beliefs about the necessity and adverse effects of the medication they take [29], and illness perceptions indicate how a patient understands his/her illness [30]. A number of theoretical frameworks suggest that these social cognitions and self-regulatory processes affect the likelihood that a person will engage in a behavior [31-34]. Therefore, we considered that these factors could potentially mediate the impact of the multifaceted intervention on behavior (i.e., medication adherence). Moreover, because QoL and mortality rate are further outcomes of medication adherence

[13,14], medication adherenceshould mediate the effect of the intervention on QoL and mortality rates.

1.1 Objectives

The present study aimedto evaluate the long-term effects of a multifaceted intervention (including psycho-education, motivational interviewing, and a short message service[SMS]) on medication adherence (primary outcome), and QoL and mortality rates (secondary outcomes) in older patients undergoing CABG surgery.In addition, we measured a number of relevant social cognitions (e.g., strength of intentions to take medication) and self-regulatory processes (e.g., action and coping planning) as potential mediators of the effects of the intervention on medication adherence.

2. Methods

This trial was registered at ClinicalTrials.gov with the registration number NCT02109523.

2.1 Design and study population

The study adopted an open-label, researcher-blind, randomized controlled design, with two arms.Specifically, one arm received multifaceted intervention (see *Section 2.3 Intervention* for more details); another received treatment as usual (see *Section 2.5 Treatment as Usual* for more details). Patientswere recruited frommultiple centers across Iran (5 academic centers in Tehran, 2 in Qazvin and Ahvaz each,1 in Semnan, Zanjan, andTabriz each). Inclusion criteria were that patients:(a) be aged 65 years or above, (b) had undergoneCABG surgery, (c)had the ability to read and write Persian/Farsi, (d)provided informed consent to participate, and (e) had access to a mobile phone. Exclusion criteria were that patients:(a) had already usedDosette boxes (or similar) to improve medication adherence, (b) were currently enrolled in another clinical trial,

(c) suffered from significant dysphasia, severe kidney disease (creatinine clearance < 30 ml/min), oxygen-dependent chronic obstructive pulmonary disease, active hepatitis, significant hepatic failure, and/ora prior peptic ulcer (platelet count < 150×10^9), (d) were having concomitant surgery,(e) suffered from a severe cognitive impairment (i.e., Mini Mental Status Examination MMSE score of< 20, (f) had had a myocardial infarction within 48hours of surgery, (g) were allergic to aspirin, (h) abused alcohol or narcotics, (i) reportedongoing bleeding, (j) had a terminal condition or were deemed unlikely to survive until six-month follow-up, (k) were not being responsible for their own medication, and (l) the CABG was conducted as an emergency surgery.Patients with poor prognosis (n=2) and those who had CABG as an emergency surgery (n=3) were excluded to increase the likelihood that we were able to measure relevant outcomes at eighteen months. Patients requiring emergency or urgent CABG are at higher risk than those undergoing CABG electively, and emergency CABG is typically carried out if serious complications develop after a heart attack (e.g., shock, life-threatening abnormalities of the heart rhythm, or rupture of heart tissues), thus there is an increased risk of mortality among such patients [9].

Five trained general practitioners assessed each participant with respect to theaforementionedinclusion and exclusion criteria, after which all eligible patientswereinvited to participate in a group information session in a seminar room in their respective hospitals. In this session, the principal investigator and a surgeon explained the aims of the study and answered any questions that the patients had. Interested patients were then asked to sign a consent form and were assigned a unique study identification (ID) number. Following this, patients completedbaselinemeasures (*n*=288patients completed this assessment). The measures were repeated at six, twelve, and eighteen months after the intervention.Ethics approval was obtained

from the review committees of the different centers and partner institutions who approved the trial (QUMS.REC.1394.2).The study was conducted in accordance with the Ottawa Statement, the Helsinki Declaration, and Good Clinical Practice.

2.2 Randomization and blinding

In order to minimize contamination and maximize the efficiency with which the intervention was delivered, centers were chosen as the units of randomization. Specifically, the centers were randomly assigned to either the intervention (EXP) or the treatment as usual (TAU) groups by an independent statistician following a 1:1 scheme using a computer generated list of random numbers. Six centers were assigned to the EXP group and six centers were assigned to the TAUgroup. Figure 1 shows the flow of patients through the study.

(Insert Figure 1 here)

The sample size needed to detect any effects of the intervention was calculated based on the primary outcome measure (self-reported medication adherence). It was estimated that 144 patients would be needed in each group to detect an effect (*difference*) = 1 score, with 90% power and a significance level of 5%, assuming a standard deviation of 1.9 in both groups, design effect of 1.8, and 5% loss at follow up. Exactly 144 patients were therefore allocated to each group as suggested by the sample size calculation.

All researchers responsible for measuring outcomes as well as statisticians were blinded to the group allocation. However, it was not possible for patients to be blind to group allocation because of the use of behavioral interventions. Therefore, objective measures of medication adherence such as total cholesterol, high-density lipoprotein (HDL) and low-density lipoprotein (LDL) concentrations were also evaluated, alongside self-reported rates of adherence to reduce the likelihood of demand effects.

2.3 Intervention

Patients in the EXP group received a multifaceted interventionthat included:(a) psycho-education, (b) motivational interviewing (MI), and (c) sending reminders via SMS. The intervention began the first week after the patients were discharged.

2.3.1 Psycho-education

Patientsin the EXP group participated in three weekly sessions accompanied by at least one family member with whom they had a close relationship (e.g., their father, mother, spouse, brother or sister).The psycho-education component of the intervention was delivered by cardiovascular nurses. The contents and topics of psycho-education were discussed and preselected by cardiovascular nurses as well as cardiologists. The content of the psycho-education was the same for all patients and delivered orally.Each session lasted for one hour and the main purpose was to provide information aboutcoronary artery disease andways of coping with the disease (e.g., the potential barriers to, and concerns about, coping with the disease). In addition, patients' experiences during previous visits, a list of previous medications and their effects and side-effects, the reasons for previous medication non-adherence, as well as the reactions and communication between the family members about the patients' symptomswere discussed.

2.3.2 Motivational interviewing (MI)

The patients in the EXP group attended five weekly sessions of MI that each lasted around 50 minutes. All sessions were held in a quiet, private, and comfortable setting inside the hospitals. The sessions were delivered by five trained and registered psychologists with experience (more than 100 hours) in moderating MI sessions. These psychologistsusedseveral

MI techniques that could potentially help the patients to increase their medication adherence, including open-ended questions, rolling with resistance, agenda setting, eliciting self-motivational statements, change talk, and affirmations. Following this, the psychologists highlighted factors that might interfere with the patients' plans to take their medication (also called: *action planning*) andasked the patients to anticipate situations in which they might struggle to take their medicationalong with possible strategies that they might use to overcome these barriers (also called:*coping planning*) [18]. At the end of the session, patients were asked to put the form on which they had written their plan(s) in a place that was easily visible and accessible for them. Detailed information on the procedure for the MI sessions is provided in Electronic Supplementary Material Table S1.

2.3.3 Reminders via SMS

Four reminders were sent to patients on a monthly basis via text messages. The content of the messages differed each month as follows: (1) The only way to improve your health is regular adherence to your medications; (2) Regular adherence to your medications will greatly help your recovery process and improve your health; (3) The most important factor for preventing a heart attack is that you take your medication regularly; and (4) Carefully considerwhich medication you take on a daily basis.

2.4 MI integrity/fidelity

In order to assess the quality and integrity of MI, all sessions were audiotaped.To evaluate integrity, the Motivational Interviewing Treatment Integrity (MITI) scale 3.1.1 was used [35]. The MITI is a widely used measure of competences in MI. It normallymakes use of a 20-minute segment of each MI session and evaluates this segment based on global scores and

behavior counts (two components of the MITI) to capture treatment fidelity.Twenty percent of the audiotaped sessions were selected randomly for evaluation by an independent/external coder.The global scores comprise five global ratings including evocation, collaboration, autonomy/support, direction, and empathy. The behavior counts include providing information, asking open- and closed-ended questions, providing simple and complex reflections, and making other statements categorized as MI adherent or not. In addition to the abovementioned components, five summary scores (i.e., each domain of the global ratings: evocation, collaboration, autonomy/support, direction, and empathy)were also computed to provide a more concise measure of competence.

Electronic Supplementary Material Table S2 provides the global measures, behavior counts, and summary scores of the MITI. All of the facilitators who delivered the MI were competent, according to this measure. Specifically, the means of global measures were between 3.61 and 4.59, and the mean percentage of facilitators who were MI adherent was 93.12. Most means were slightly below competency, but above beginning proficiency.

2.5 Treatment as Usual

Patients allocated to thetreatment as usual(TAU)group received the advice commonly given by surgeons oncoronary artery diseaseand the CABG procedure, along with information on the importance of healthy diet and nutrition. Patients in the TAU group were further informed about the importance of medication adherence and encouraged to regularly take their medications, as well as being reminded of the negative consequences of nonadherence. Providing this information tookapproximately 30 minutesand took place in a room in the respective hospitals before the patients' discharge.

2.6 Outcomes

All outcomes were measured at baseline (before the intervention), andthensix, twelve, and eighteen months post-surgery. Detailed information on each of the measures is described below. The measures of intentions, action and coping planning, perceived behavioral control, and self-monitoring were based on similar measures used in previous research [18,25-30], but were adapted so as to be relevant for Iranian patients undergoing CABG.

2.6.1 Medication Adherence Rating Scale

The Medication Adherence Rating Scale (MARS)is a short self-report scale measuring medication adherence that consists of 5 items which patients are asked to respond to on a 5-point Likert scale (from 1: always to 5: never) [36]. Scores range from 5 to 25 with higher scoresindicating better medication adherence [18]. The Persian version of the MARSin the current studyproved internally consistent (Cronbach's α=0.89).

2.6.2 Pharmacy refill rate

The pharmacy refill rate was defined as the number of days on which medications were dispensed to the patient during the study period, divided by the total number of days in the study period. This figure was then multiplied by 100 to give a percentage. All related information was collected monthly from 22 pharmacies in 6 cities and included the total number of pills prescribed along with the dates of each prescription. We assessed the cardiovascular medication adjusted for inpatient days and medication refills prior to enrollment date as well as information registered at six and twelve months' follow-up on change in prescriptions.

2.6.3 Lipid profile

Serum lipid profiles were determined for all patients by taking 5ml of venous blood after overnight fasting. Total cholesterol (TC), triglycerides (TG) and high-density lipoprotein-cholesterol (HDL-C) concentrations were determined by the enzymatic colorimetric method. Low-density lipoprotein-cholesterol (LDL-C) concentration, as well as serum TC, TG and HDL-C concentrations were calculated using the Friedewald formula.

2.6.4 Intentions

Patients completed a short (5-item) questionnaire designedto measure their intentions to take medication, with items (e.g., "I intend to regularly take medicine in the future") beingresponded to on a 5-point Likert-type scale (from 1: completely disagree to 5: completely agree) [18].The measure of intentions showedsatisfactory internal consistency in this study (Cronbach's α=0.90).

2.6.5 Self-report Behavioral Automaticity Index

The Self-report Behavioral Automaticity Index (SRBAI)measures the extent to which a particular behavior (e.g., taking medication) is automatic for an individual [25]. The SRBAIconsists of four statements that begin with "Behavior X is something…", followed bydifferent descriptions, such as "I do automatically"; "I do without having to consciously remember"; "I do without thinking"; "I start doing before I realize I am doing it". Patients are asked torate the extent to which they agree with each of the statements on a 5-point Likert-type scale (from 1: disagree to 5: agree), and items were summed. The Persian version of the SRBAI was found to be highly reliable in this study (Cronbach's $\alpha = 0.91$).

2.6.6 Action and coping planning

Four items were used to measure action planning: “I have made a detailed plan regarding when / where / how often /how to take medication. Another four items were used to measure coping planning. Patients were provided withthe stem: “I have made a detailed plan regarding…” followed by four different endings: “…what to do if something interferes”; “…what to do if I forgot it”; “…how to motivate myself if I don’t feel like it”; “…how to prevent being distracted” [26].All items were rated on a 5-point Likert-type scale (1: completely disagree to 5: completely agree) and both the measures of action planning (Cronbach’s α=0.93) and coping planning (Cronbach’s α=0.91) proved internally consistent.

2.6.7 Perceived behavioral control

Perceived behavioral control (PBC)was measured with four items, to which patients responded on5-point Likert-type scales. Items included: “For me to take regular medication in the future is…” (1: difficult to 5: easy) and “It is up to me to take regular medication…”(1: strongly disagree to 5: strongly agree) [26].The measure of PBC proved internally consistent in this study (Cronbach’s α=0.93).

2.6.8 Self-monitoring

Self-monitoring was measured using three items on a scale that ranged from 1 (strongly disagree) to 5 (strongly agree). Each item consisted of a main sentence: “During the last month, I have consistently monitored…” with ending variations being: (a) “…when to take medications”,(b)“…how often to take medications”, and (c)“…how to take medications” [27].The internal consistency of self-monitoringin the present study was acceptable (Cronbach’s α=0.82).

2.6.9 Beliefs about medicines

Patients' beliefs about medication were measured using the Beliefs about Medicines Questionnaire (BMQ). Although the BMQ has specific and general sections,only the specific section,which is thought to be associated with adherence, was used in the present study [26]. The BMQ-specific reflects beliefs in two domains– necessity and concerns – and patients are asked torespond to statements reflecting each(e.g., "My health in the future will depend on my medication" [necessity] and "My medication disrupts my life" [concerns]) on a 5-point Likert-type scale (from 1: strongly disagree to 5: strongly agree). Scores on each domain can range from 5 and 25 with higher scoresrepresentingmore worryabout taking medicine. A study with an Iranian sample with diabetes used the Persian version of BMQ,andshowed satisfactorypsychometric properties [29]. The internal consistency of the BMQ-Necessity and BMQ-Concernsin the present study were Cronbach's $\alpha = 0.83$ and Cronbach's $\alpha = 0.85$, respectively.

2.6.10 Brief Illness Perception Questionnaire

The Brief Illness Perception Questionnaire(BIPQ) consists of 9 items that assess illness perceptionsin the following areas: Identity, consequences, timeline, personal control, treatment control, concern, understanding, illness comprehensibility, and emotional representations [30]. Each item is rated on an 11-point Likert scale, where a higher score represents a higher level of illness perception. We used the total score (i.e., summing responses across each of the 9 items), which represents the degree to which the illness is perceived as threatening or benign [30].The internal consistency of the BIPQ in the present study was acceptable (Cronbach's $\alpha = 0.86$).

2.6.11 Health related quality of life: Short-Form 36

The Health related quality of life: Short-Form 36 (SF-36) includes 36 items, measuring bothphysical (PCS; sample item: “In general, would you say your health is…”) and mental (MCS; sample item: “Have you felt calm and peaceful?”) health. The scores were converted into a 0-100 scale, with higher scores indicating better QoL [37,38]. The SF-36 has been translated into Persian and has been validated in a sample of Iranian hemodialysis patients showing satisfactory psychometric properties [39]. The internal consistencies of SF-36 subscales in the present study were acceptable and ranged from Cronbach’s $\alpha = 0.74$ to Cronbach’s $\alpha = 0.93$.

2.7 Statistical Analysis

Background information, clinical characteristics, and all outcome measuresare described using means and standard deviations (*SD*) for continuous variables and frequency and/or percentages (%) for categorical variables. Multilevel linear mixed modelswere used to investigate the efficacy of the intervention taking into account the hierarchical nature of the data (i.e., that the patients were clustered in different centers) and repeated measures (i.e., that a number of outcomes were measured at several time points). Intention to treat (ITT) analysis was used, such that outcomes among all patients allocated to the groups were analyzed, whether they completed the intervention or not.We used three levels of analysis (repeated measures as the first, patients as the second, and centers as the third levels) with a restricted iterative generalized least square (RIGLS) estimation. This RIGLS computesunbiased estimates of the random parameters. In addition, we used univariate multilevel analyses to investigate the effects of potential confounding variablesincluding age, education, family income, and body mass index. Confounding variables with a p value< 0.20 were controlled for in the multivariate models.As consequence, each model was adjusted for the following potential confounding variables: age, sex, Charlson comorbidity index, and body mass index.

Potential mediators of the relationship between the intervention and medication adherence and between the intervention and QoL were examined using Sobel tests. Finally, survival analyses accounting for cluster effects of the hospitals were performed, with the cluster effects of centers being adjusted.All tests were two-tailed using a significance level of <0.05. Benjamini and Hochberg false discovery rate was used to adjust p-values for multiple comparisons where appropriate. Multilevel linear mixed modelingwas conducted using MLwiN 2.27 software. Survival analyses were performed usingthe survival package in R (R Core Team, 2014).

3. Results

After screening a total of 462 patients, 288 patients from 12 centers were eligible to participate in the study and the centers were randomly assignedto either the TAUor the EXPgroups(Figure 1).Thirty-five patients in the two groups dropped out during treatment.Table 1 summarizes the baseline and clinical characteristics of the two groups. The mean age of patients in the TAU group was 75.23 (*SD* = 5.82) years and 74.32 (*SD* = 5.26) years for the EXP group and nearly two thirds of the patientswere male (65.3% in TAU and 67.4% in EXP).

(Insert Table 1 here)

The descriptive statistics formedication adherence (including the MARS, objective pharmacy refill rate, and serum level of lipid profile), beliefs about medication, and QoL across the 18 months are reported in Table 2. Overall, patientsin the EXP groupshowed better medication adherence after six months compared to patientsin the TAU group, as indicated by the MARS (baseline: 7.68±2.45 in EXP and 7.62±2.76 in TAU; six months: 13.67±2.80 in EXP and 7.69 in TAU), pharmacy refill rate (baseline: 62.30±16.22%in EXP and 61.41±16.30% in

TAU; six months: 73.81±18.56% in EXP and 63.14±17.21% in TAU), HDL-C (baseline: 34.54±9.89% in EXP and 34.42±9.74% in TAU; six months: 42.74±10.41% in EXP and 34.18±9.38% in TAU), and LDL-C (baseline: 113.75±33.06 mg/dLin EXP and 115.20±32.76mg/dL in TAU; six months: 99.26±36.75 mg/dLin EXP and 110.01±35.78 mg/dLin TAU). Furthermore, medication adherence did not decrease after eighteen months in the EXP group and patients in this group reported slightly better QoL, including PCS and MCS, than patients in the TAU group after six months.

(Insert Table 2 here)

After considering multicenter and other potential confounding factors and effects, the three-level multiple linear regression models showed that patients in the EXP group had better medication adherence after six, twelve, and eighteen months compared to patients in the TAU group (see Table 3) as indicated by the MARS (B = 3.97 at six months, 3.83 at twelve months, and 4.24 at eighteen months; $p< 0.01$), pharmacy refill rate (B = 9.82% at six months, 10.64% at twelve months, and 10.40% at eighteen months; $p < 0.01$), total cholesterol (B = -7.40 mg/dL at six months, -8.77mg/dL at twelve months, and -8.60 mg/dL at eighteen months; $p < 0.01$), LDL-C (B= -12.45 mg/dL at six months, -13.71 mg/dL at twelve months, and -13.59 mg/dL at eighteen months; $p < 0.01$), HDL-C (B = 8.41 mg/dL at six months, 8.71mg/dL at twelve months, and 8.87 mg/dL at eighteen months; $p < 0.01$), and triglycerides (B = -16.83 mg/dL at six months, -18.86mg/dL at twelve months, and -18.21 mg/dL at eighteen months; $p < 0.01$).

(Insert Table 3 here)

About 11.1% of the patients in the TAU group and 4.2% of the patients in the EXP group had died before theend of follow-up (Figure 2). When considering the loss at follow-up and

drop-outs, a Gamma frailty survival model on the time of death showed that the crude hazard ratio (HR) in the EXP compared to the TAU group was 0.36 (95% CI: 0.14 to 0.91, p=0.036). After adjusting for the effects of age, sex, and number of diseased vessels, this hazard ratiocontinued to show a lower rate of death in the EXP group compared to the TAU group (adjusted HR = 0.38, 95% CI: 0.15to 0.97, p=0.044).

(Insert Figure 2 here)

Electronic Supplementary Material Tables S3 and S4 show the effects of intervention on intentions, perceived behavioral automaticity, self-monitoring, action and coping planning, beliefs about medicines, illness perceptions, and QoL. Patients in the EXP group reported better QoL than did patients in the TAU group after eighteen months (B = 1.77 and p = 0.02 for PCS; B = 1.68 and p = 0.04 for MCS). The interactions between group and time tended to be significant such that patients in the EXP group (relative to those in the TAU group) tended to have more positive beliefs about taking medication, reported stronger intentions to take medication, and had perceptions of increased control over medication use. They were also more likely to have formed action and coping plans to support medication adherence and self-monitor their medication use; and reported that taking medication had become relatively automatic for them.Social cognitions and self-regulatory processes all mediated the effects of the intervention on mediation adherence (See Electronic Supplementary Material Table S5). An additional mediation analysis showed that medication adherence mediated the effects of the intervention on outcomes such as QoL and survival rates.

4. Discussion

The present findings suggest that a multifaceted intervention with three components (psycho-education, motivational interviewing [or MI], and SMS reminders) can improve medication adherence, QoL, and mortality ratesamong olderpatients undergoing CABGsurgery. Specifically, patients who received the multifaceted intervention program (i.e., patients in the EXP group) showed increased MARS scores and higher pharmacy refill rates six- and eighteen-months post-surgery. In contrast, MARS scores and pharmacy refill ratesdid not increase among patients who received conventional treatment and information (i.e., among patients in the TAU group). Othermeasures used to objectively assess medication adherence (including total cholesterol, HDL-C, TDL-C, and triglycerides) supported these conclusions and showed that patients in the EXP group were in betterphysiological health than were patients in the TAU group in the six to eighteen month after the intervention. In addition to medication adherence, patients who received themultifaceted intervention also reported betterQoL andhad a higher life expectancy compared to patients in the TAU group.

Previous studies have also reported beneficial effects of MI on medication adherence, albeit among different samples than those studied here, such as older people (aged 53-73 years) [40] and people with epilepsy [26].Furthermore, previous studies attest to the efficacy of combining medical counseling with planning for promoting medication adherence among patients undergoing CABG [18]. However, although a number of studies have shown the beneficial effects of such interventions, the current study combined the intervention components and, perhaps as a result, seemed to be even more effective in increasing medication adherence in older patients (d =2.13 in the present research; d = 0.30 to 1.02 in previous studies [18, 26, 40]). In short, the present findingssupport the effects of similar interventionsconducted in

otherpopulations [21,26,40],such as patients with epilepsy, and show that MI andcounseling can effectively enhance medication adherence in older individuals [41-44].

The present research also builds on previous studies by showing that a multifaceted intervention not only increases medication adherence but, as a result, can improveQoL and increaselife expectancy in olderpatients receiving CABG. Interestingly, theeffects on QoLwere only observed at eighteenmonths post-surgery,compared to the changes in medication adherence,which were observed at sixmonths after surgery.However, this is to be expected given that both previous and the present research show that QoL is influenced by medication adherence and thus takes time to change [45-47]. In terms of the effects of the intervention on survival rates, previous studies have demonstrated that psycho-education and MI can reduce mortality in patients with different diseases [48-50],including coronary heart disease patients. Our results echo suchfindings andfurthersupport the idea that the combination of psycho-education and MI can improve survival rates through medication adherence.

4.1 Strengths and limitations

There are several strengths to our study. First, an eighteen-month follow-up without further intervention was used to investigate the long-term effects of the intervention on medication adherence and a number of health-related outcomes in patients undergoing CABG. As such, the findingsprovide important insights for clinicians in regards to the long-term effects of such interventions, not only on medication adherence but also on patients' overall health and QoL. Second, the present study included a variety of objective outcome measures to assess medication adherence and did not rely on self-report alone; therefore minimizing social desirability and reporting biases. Third, robust statistical analyses were conducted that accounted

for potential confounding variables. By using multilevel linear mixed models,shared variance (e.g., accruing from recruiting patients from the same hospital) were minimized [51].

However, there are also some limitations that need to be considered when interpreting the findings. First, the effects of the intervention may not be generalizable to Western countries and cultures, particularly asthe present researchincorporated an element of family engagement. Unlike Western cultures thattend to emphasizeindividualism [52],family plays a crucial role for people with a Middle Eastern cultural background [53].Second, patients with serious and/or specific health conditions (e.g., suffering from cognitive impairment or froma severe kidney disease) were excluded from the present research. Therefore, the findings may not generalizeto other patients undergoing CABG who have additional health problems. Further studies are therefore warranted to investigate the effects of similar interventions in such groups. Third, because the present research developed and implemented amultifaceted intervention, the individual effects of each component cannot be separated. In other words, it is unclear which of the three components (psycho-education, MI, and SMS reminders) were effective in promoting medication adherence, and could potentially be used as individual components, or whether the outcomes were dependent on a joint effect. The larger effect size reported in the present research, relative to other studies that tested the effects of interventions that only incorporated one or some of these components suggest that the multifaceted intervention was particularly beneficial, but factorial designs that directly compare interventions with different components are needed corroborate this assertion. Lastly, the intervention used in the present research was relatively intensive and required a substantial time commitment from both the patients and those delivering the intervention. Although the findings were promising, further research could evaluate the cost-

effectiveness of the intervention relative to, for example, less complex interventions. Again, a factorial design would appear to be appropriate for this purpose.

5. Conclusion

In conclusion, the findings of the present study suggest that a multifaceted intervention consisting ofpsycho-educational, MI, and SMS reminders can promote medication adherence in older patients undergoing CABG, and that these effects are maintained eighteenmonths post-surgery. The increase in medication adherence as a function of the intervention also improved other health-related outcomes. Clinicians may therefore consider using multifaceted interventions to improve health and survival rates in older patients undergoing CABG.

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Figure Legends

Fig. 1: Flow diagram for random assignment of patients in the study.MMSE = Mini Mental Status Examination; CABG = coronary artery bypass graft

Fig. 2: Survival rates for patients in multifaceted intervention group (EXP) and those in treatment as usual group (TAU).

Supplementary Materials Legends

Electronic Supplementary Material TableS1: The procedure for Motivational interviewing (MI) sessions.

Electronic Supplementary Material TableS2: MITI global measures, behavior counts, and summary scores.

Electronic Supplementary Material TableS3: Three-level multiple linear regression models predicting intention, perceived behavioral control, behavioral automaticity, self-monitoring, action planning and coping planning.

Electronic Supplementary Material TableS4: Three-level multiple linear regression models predicting beliefs about medicines, illness perceptions, and quality of life (QoL).

Electronic Supplementary Material TableS5: Direct and mediated effects of group on medication adherence, quality of life (QoL) and survival rates.

Tables

Table 1

Comparison of clinical characteristics between the intervention (EXP) and treatment as usual (TAU) groups at baseline

	Treatment as usual (n = 144)	Intervention (n = 144)
Age, years; median (IQR)	76 (70-80)	75 (69-79)
Years of education; median (IQR)	4 (1-12)	4 (1-12)
Household income, rials[a]; median (IQR)	848.65 (453.40-1295.44)	893.06 (942.88-1286.88)
Body mass index, kg/m^2; mean±SD	28.84±5.57	28.64±4.03
Marital status; n (%)		
Single	4 (2.8%)	6 (4.2%)
Married	90 (62.5%)	92 (63.9%)
Divorced/widowed	50 (34.7%)	46 (31.9%)
Sex; n (%)		
Male	94 (65.3%)	97 (67.4%)
Female	50 (34.7%)	47 (32.6%)
Ejection fraction; mean±SD	45.23±6.12	44.82±7.02
Cross clamp time, minutes; mean±SD	52.42±25.81	54.21±27.62
Cardiopulmonary bypass duration time, minutes; mean±SD	96.68±39.42	97.92±40.35
Cardiac risk factors; n (%)		
Diabetes mellitus	55 (38.2%)	52 (36.1%)
Hypertension	107 (74.3%)	110 (76.4%)
Dyslipidemia	61 (42.4%)	52 (36.1%)
Myocardial infarction	86 (59.7%)	90 (62.5%)
Chronic lung disease	17 (11.8%)	15 (10.4%)
Prior cardiac surgery; n (%)	12 (8.3%)	9 (6.2%)
Current smoker; n (%)	21 (14.6%)	18 (12.5%)
No. of major vessels/branches bypassed; n (%)		
1 vessel	21 (14.6%)	14 (9.7%)
2 vessels	49 (34.0%)	46 (31.9%)

3 vessels	74 (51.4%)	84 (58.3%)
CCSC; n (%)		
I	12 (8.3%)	10 (6.9%)
II	24 (16.7%)	15 (10.4%)
III	48 (33.3%)	51 (35.4%)
IV	60 (41.7%)	68 (47.2%)
Charlson comorbidity index; n (%)		
0	40 (27.8%)	36 (25.0%)
1-3	79 (54.9%)	81 (56.2%)
≥4	25 (17.4%)	27 (18.8%)
Medications; n (%)		
Aspirin	135 (93.8%)	132 (91.7%)
Beta blockers	115 (79.9%)	122 (84.7%)
Angiotensin converting enzyme inhibitors	98 (68.1%)	90 (62.5%)
Lipid lowering	105 (72.9%)	109 (75.7%)
Number of centers	6	6
Number of patients in each center	24	24

Note. IQR = interquartile range, SD = standard deviation, CCSC: Canadian Cardiovascular Society Classification

[a] 3,500 rials = US $1 (April 2016)

Table 2

Descriptive statistics for all outcome measures across time in the intervention group (EXP) and the treatment as usual (TAU) group

Variable (normal range)	Group	Mean (SD) Baseline	Month 6	Month 12	Month 18
BMQ-Necessity (5-25)	TAU	14.62 (3.22)	14.54 (3.30)	14.41 (2.42)	14.40 (3.07)
	EXP	14.37 (2.24)	18.69 (2.49)	18.64 (2.48)	18.53 (2.57)
BMQ-Concerns (5-25)	TAU	13.23 (4.05)	13.27 (4.0)	13.31 (4.27)	13.33 (4.12)
	EXP	12.92 (3.29)	7.81 (3.22)	6.02 (3.09)	4.78 (3.01)
Perceived behavioral control (1-5)	TAU	2.50 (0.93)	2.43 (0.98)	2.41 (0.99)	2.40 (0.93)
	EXP	2.49 (0.89)	3.00 (1.10)	2.98 (1.01)	2.99 (1.12)
Intention (1-5)	TAU	2.67 (0.65)	2.73 (0.69)	2.70 (0.70)	2.69 (0.69)
	EXP	2.72 (0.74)	3.44 (1.03)	3.41 (1.01)	3.42 (1.13)
Self-monitoring (1-5)	TAU	1.94 (0.40)	1.92 (0.51)	1.96 (0.75)	1.91 (0.82)
	EXP	2.06 (0.54)	2.65 (1.00)	2.67 (1.04)	2.66 (1.02)
Action planning (1-5)	TAU	1.93 (0.58)	1.190 (0.52)	1.88 (0.50)	1.86 (0.61)
	EXP	1.88 (0.57)	2.73 (1.13)	2.71 (1.30)	2.74 (1.29)
Coping planning (1-5)	TAU	1.68 (0.51)	1.64 (0.56)	1.61 (0.52)	1.62 (0.60)
	EXP	1.64 (0.54)	2.49 (1.11)	2.48 (1.19)	2.50 (1.26)
Self-report Behavioral Automaticity Index (1-5)	TAU	1.91 (0.80)	1.87 (0.82)	1.86 (0.99)	1.83 (1.01)
	EXP	1.86 (0.87)	2.39 (0.94)	2.40 (0.98)	2.40 (1.14)
MARS (5-25)	TAU	7.62 (2.76)	7.69 (2.70)	7.71 (2.79)	7.63 (2.88)
	EXP	7.68 (2.45)	13.67 (2.80)	13.61 (2.82)	13.70 (2.75)
Illness perception (0-90)	TAU	36.43 (11.67)	35.57 (11.66)	36.63 (11.54)	36.67 (11.47)
	EXP	37.07 (11.78)	33.93 (12.53)	33.80 (12.72)	33.46 (10.17)
Pharmacy refill rate (0-100)	TAU	61.41 (16.30)	63.14 (17.21)	62.03 (18.77)	62.03 (18.77)
	EXP	62.30 (16.22)	73.81 (18.56)	73.48 (18.44)	73.24 (15.33)
Quality of life: PCS (0-100)	TAU	46.07 (11.66)	48.23 (11.70)	47.88 (12.05)	47.08 (10.10)
	EXP	46.88 (10.68)	50.04 (12.41)	50.29 (12.69)	49.93 (9.65)
Quality of life: MCS (0-100)	TAU	43.42 (12.76)	46.77 (11.41)	46.82 (11.33)	46.48 (10.35)
	EXP	44.92 (10.14)	49.39 (12.60)	49.76 (10.93)	49.69 (11.84)
Total cholesterol concentration (mg/dL)	TAU	182.90 (38.69)	180.76 (33.89)	180.71 (33.51)	180.53 (35.81)
	EXP	181.85 (39.00)	172.32 (40.71)	170.92 (32.12)	171 (32.00)

HDL-C (mg/dL)	TAU	34.42 (9.74)	34.18 (9.38)	33.88 (10.52)	33.52 (8.16)
	EXP	34.54 (9.89)	42.74 (10.41)	42.63 (11.29)	42.41 (9.31)
LDL-C (mg/dL)	TAU	115.20 (32.76)	110.01 (35.78)	113.32 (35.57)	114.51 (35.65)
	EXP	113.75 (33.06)	99.26 (36.75)	98.26 (27.32)	98.69 (27.41)
Triglycerides (mg/dL)	TAU	166.37 (66.60)	167.07 (65.99)	167.52 (55.43)	165.27 (65.21)
	EXP	167.61 (69.38)	151.55 (66.55)	150.13 (58.05)	149.33 (68.90)

Note. BMQ= Beliefs about Medicines Questionnaire; MARS= Medication Adherence Rating Scale; PCS= Physical Component Summary; MCS= Mental Component Summary; HDL-C = high-density lipoprotein cholesterol; LDL-C = low-density lipoprotein cholesterol

Table 3

Three-level multiple linear regression models predicting medication adherence

Variable	MARS		Pharmacy refill rate		Total cholesterol		LDL-C		HDL-C		Triglycerides	
	B (SE)	*p* value	B (SE)	*p* value	B (SE)	*p* value	B (SE)	*p* value	B (SE)	*p* value	B (SE)	*p* value
Group (Ref: TAU)	0.30 (0.66)	0.36	2.37 (2.62)	0.26	-3.30 (7.25)	0.36	-3.01 (5.94)	0.35	15.52 (5.64)	**0.01**	-4.54 (9.73)	0.36
Time (Ref: baseline)												
6 months	0.38 (0.16)	**0.02**	1.81 (0.66)	**0.01**	-2.21 (1.34)	0.10	-2.22 (1.29)	0.09	0.12 (0.43)	0.38	-0.61 (1.79)	0.38
12 months	0.30 (0.14)	**0.045**	0.66 (0.46)	0.14	-2.26 (1.60)	0.15	-1.97 (1.31)	0.13	0.54 (0.40)	0.16	-1.21 (1.94)	0.33
18 months	0.05 (0.16)	0.38	0.91 (0.78)	0.20	-2.45 (1.60)	0.12	-1.79 (1.30)	0.16	0.92 (0.31)	**0.01**	-1.38 (1.86)	0.30
Group×time												
EXP vs. TAU at 6 months	3.97 (0.22)	**<0.01**	9.82 (0.93)	**<0.01**	-7.40 (1.88)	**<0.01**	-12.45 (1.80)	**<0.01**	8.41 (0.60)	**<0.01**	-16.83 (2.52)	**<0.01**
EXP vs. TAU at 12 months	3.83 (0.23)	**<0.01**	10.64 (0.95)	**<0.01**	-8.77 (1.92)	**<0.01**	-13.71 (1.93)	**<0.01**	8.71 (0.73)	**<0.01**	-18.86 (2.80)	**<0.01**
EXP vs. TAU at 18 months	4.24 (0.26)	**<0.01**	10.40 (0.98)	**<0.01**	-8.60 (1.99)	**<0.01**	-13.59 (1.78)	**<0.01**	8.87 (0.60)	**<0.01**	-18.21 (2.70)	**<0.01**
Age	-0.19 (0.14)	0.17	-0.13 (0.13)	0.25	1.40 (1.41)	0.24	0.61 (1.23)	0.35	-0.92 (0.35)	**0.01**	0.46 (1.91)	0.39
Sex (Ref: females)	0.33 (0.47)	0.31	-8.32 (2.58)	**<0.01**	2.52 (1.63)	0.12	5.16 (3.68)	0.15	0.12 (0.10)	0.20	0.62 (0.86)	0.31
Charlson comorbidity index	-0.92 (0.65)	0.15	-1.69 (0.75)	**0.03**	9.59 (7.22)	0.17	-11.85 (6.91)	0.09	-6.64 (1.49)	**<0.01**	2.28 (0.98)	**0.03**
Body mass index	-0.06 (0.04)	0.16	-0.31 (0.61)	0.35	3.26 (1.26)	**0.01**	1.76 (4.01)	0.36	-0.35 (0.19)	0.07	8.37 (0.91)	**<0.01**
Intercept	11.14 (2.32)	**<0.01**	55.19 (8.66)	**<0.01**	164.84 (23.06)	**<0.01**	11.02 (2.26)	**<0.01**	15.21 (5.64)	**0.01**	187.83 (45.75)	**<0.01**
$\hat{\sigma}^2_{st}$ (patients)	14.97 (0.96)	**<0.01**	103.90 (13.19)	**<0.01**	46.70 (9.18)	**<0.01**	53.59 (8.41)	**<0.01**	93.12 (5.98)	**<0.01**	46.91 (15.61)	**<0.01**

$\hat{\sigma}^2_{sc}$ (centers)	3.52 (0.12)	**<0.01**	32.08 (11.64)	**0.01**	26.23 (8.58)	**<0.01**	37.21 (6.81)	**<0.01**	9.49 (3.88)	**0.02**	24.92 (16.10)	**0.12**

Note. Ref. = reference group for comparison; TAU=treatment as usual group; EXP= intervention group; MARS= Medication Adherence Rating Scale; LDL-C= low-density lipoprotein cholesterol; HDL-C= high-density lipoprotein cholesterol; $\hat{\sigma}^2_{st}$ = the variance at patient level; $\hat{\sigma}^2_{sc}$ = the variance at center level; SE = standard error.
p values < 0.05 are in **bold**

Electronic Supplementary Material Table S1. The procedure for motivational interviewing (MI) sessions.

First session	The facilitator introduced himself/herself to the patients and assured them that the conversations would be kept private. The facilitators then elicited problems that the patients faced by asking questions such as "How do you describe your problem?"; "What do you think has caused your problem?"; "What do you fear most about your illness?". Patients had the chance to describe their condition(s) and talk about their concerns with the facilitator. The facilitators further encouraged the patients to discuss any concerns that may interfere with their willingness and/or motivation to adhere to their medication. Facilitators also provided specific information on the medication that patients were asked to take (e.g., dosage and timing, adverse effects, contradictions, and treatment process).
Second session	The patients were encouraged to talk about their feelings regarding their condition and medication adherence. Open ended questions, including "How have things gone this week?" and "How have you been feeling?" were used to assess the patient's feelings during the past week (e.g., feelings about new stressors, changes in condition, etc.). Facilitators also inquired about the patients' adherence and their reaction to the medication to obtain an overall impression of the emotional experiences of the patients.
Third session	The third session focused on helping the patients to evaluate the perceived costs and benefits of medication adherence. The goal was to identify the positive and negative consequences of taking medication, (e.g., "What do you see as the positive and negative consequences of taking medication?" and "What are some of the long-term and short-term effects of regularly taking your medication?"). Alternative courses of action were also considered during this session. For example, patients were encouraged to think about what the future would look like if they adhered to their medication. Questions to illicit these thoughts were e.g. "If you are successful in regularly taking medicine, how could things be different in the future?", or "What will be the impact on your quality of life?".
Fourth session	The fourth session focused on the patients' values and goals. The facilitators assisted the patients in recognizing and attaining their values and goals by encouraging them to engage in confidence talk to increase their motivation for medication adherence.
Fifth session	The facilitators helped the patients to review their progress, reinforce their motivation and recognize their success in adherence. Following this, the patients were advised to keep a daily diary and to note the frequency of the medications that they have to take. The facilitators also encouraged the patients to form specific plans and identify strategies that would help them to take their medication (i.e., action planning). They were then asked to imagine themselves in this specific situation and evaluate how their strategies might help them to remember to take their medication. The patients wrote their plans on a form and were encouraged to sign it and consider it as a contract.

Electronic Supplementary Table S2. MITI global measures, behavior counts and summary scores.

Measurers	Mean ±*SD* *(n=140)*	Minimum	Maximum	Beginning proficiency	Competency
Global measures					
Evocation	4.12 (0.72)	1	5		
Collaboration	3.61 (0.51)	1	5		
Autonomy/support	3.98 (0.58)	1	5		
Direction	4.23 (0.67)	1	5		
Empathy	4.59(0.71)	1	5		
Behavior counts					
Giving information	0.65 (0.39)	0	6		
MI-Adherent	7.93 (3.12)	0	25		
MI-Non-adherent	1.02 (0.93)	0	5		
Closed questions	12.39 (8.65)	0	38		
Open questions	18.81 (4.43)	0	41		
Simple reflections	16.28 (9.10)	0	61		
Complex reflections	12.02 (6.12)	1	35		
Summary scores					
Global spirit rating	3.93(0.52)	1.97	4.95	3.5	4
Percentage of complex reflections	47.69 (12.88)	10.00	100.00	40%	50%
Percentage of open questions	62.57(16.34)	25.39	100.00	50%	70%
Reflection-to-question ratio	1.05 (2.13)	0.31	16.35	1	2
Percentage MI-Adherent	93.12(8.20)	61.08	100.00	90%	100%

Note. MITI= Motivational Interviewing Treatment Integrity; MI=motivational interviewing

Electronic Supplementary Material Table S3. Three-level multiple linear regression models predicting intention, perceived behavioral control, behavioral automaticity, self-monitoring, action planning and coping planning.

Variable	INT		PBC		SRBAI		SM		AP		CP	
	B (SE)	p value	B (SE)	p value	B (SE)	p value	B (SE)	p value	B (SE)	p value	B (SE)	p value
Group (Ref: TAU)	0.06 (0.12)	0.35	0.12 (0.18)	0.32	0.02 (0.08)	0.38	0.09 (0.15)	0.34	0.14 (0.13)	0.21	0.14 (0.12)	0.20
Time (Ref: baseline)												
6 months	0.06 (0.04)	0.13	0.06 (0.04)	0.11	0.04 (0.04)	0.22	0.02 (0.02)	0.24	0.01 (0.03)	0.37	0.02 (0.05)	0.37
12 months	0.03 (0.03)	0.30	0.08 (0.02)	**<0.01**	0.04 (0.03)	0.15	0.06 (0.05)	0.21	0.04 (0.05)	0.28	0.05 (0.04)	0.21
18 months	0.02 (0.03)	0.34	0.10 (0.04)	**0.01**	0.09 (0.04)	0.051	0.08 (0.04)	**0.049**	0.06 (0.05)	0.18	0.07 (0.08)	0.28
group × time												
EXP vs. TAU at 6 months	0.61 (0.05)	**<0.01**	0.58 (0.05)	**<0.01**	0.57 (0.05)	**<0.01**	0.54 (0.06)	**<0.01**	0.84 (0.06)	**<0.01**	0.85 (0.07)	**<0.01**
EXP vs. TAU at 12 months	0.61 (0.06)	**<0.01**	0.57 (0.06)	**<0.01**	0.47 (0.06)	**<0.01**	0.54 (0.06)	**<0.01**	0.87 (0.07)	**<0.01**	0.87 (0.06)	**<0.01**
EXP vs. TAU at 18 months	0.63 (0.05)	**<0.01**	0.61 (0.06)	**<0.01**	0.50 (0.06)	**<0.01**	0.58 (0.06)	**<0.01**	0.93 (0.07)	**<0.01**	0.95 (0.08)	**<0.01**

Age	-0.03 (0.02)	**<0.01**	0.01 (0.03)	0.38	0.03 (0.03)	0.25	-0.04 (0.02)	0.07	-0.02 (0.03)	0.28	-0.03 (0.03)	0.27
Sex (Ref: females)	-0.11 (0.09)	0.17	0.21 (0.20)	0.23	0.03 (0.02)	0.14	-0.28 (0.15)	0.07	-0.17 (0.10)	0.09	-0.16 (0.09)	0.09
Charlson comorbidity index	-0.35 (0.12)	**<0.01**	-0.30 (0.08)	**<0.01**	-0.09 (0.02)	**<0.01**	-0.20 (0.10)	0.06	-0.47 (0.13)	**<0.01**	-0.46 (0.14)	**<0.01**
Body mass index	0.05 (0.08)	0.34	-0.054 (0.10)	0.59	-0.03 (0.05)	0.34	-0.01 (0.07)	0.39	-0.05 (0.09)	0.33	-0.05 (0.93)	0.40
Intercept	3.27 (0.42)	**<0.01**	2.49 (0.52)	**<0.01**	2.20 (0.49)	**<0.01**	2.86 (0.38)	**<0.01**	2.60 (0.47)	**<0.01**	2.37 (0.49)	**<0.01**
$\hat{\sigma}^2_{st}$ (patients)	0.50 (0.03)	**<0.01**	0.67 (0.04)	**<0.01**	0.61 (0.04)	**<0.01**	0.30 (0.02)	**<0.01**	0.58 (0.04)	**<0.01**	0.58 (0.04)	**<0.01**
$\hat{\sigma}^2_{sc}$ (centers)	0.06 (0.02)	**0.02**	0.22 (0.07)	**<0.01**	0.17 (0.05)	**<0.01**	0.13 (0.04)	**<0.01**	0.09 (0.03)	**0.01**	0.09 (0.03)	**0.01**

Note. Ref. = reference group for comparison; TAU = treatment as usual group; EXP = intervention group; INT = intention. PBC = Perceived behavioral control; SRBAI = Self-report Behavioral Automaticity Index; SM = Self-monitoring; AP = Action planning; CP = Coping planning; $\hat{\sigma}^2_{st}$ = the variance at patient level; $\hat{\sigma}^2_{sc}$ = the variance at center level; SE = standard error.

p-values< 0.05 are in **bold**

Electronic Supplementary Material Table S4. Three-level multiple linear regression models predicting beliefs about medicines, illness perceptions, and quality of life (QoL).

Variable	BMQ-Necessity		BMQ-Concerns		Illness perceptions		QoL: PCS		QoL: MCS	
	B (SE)	p value	B (SE)	p value	B (SE)	p value	B (SE)	p value	B (SE)	p value
Group (Ref: TAU)	0.35 (0.70)	0.35	-0.24 (0.66)	0.37	-0.17 (1.54)	0.40	1.11 (1.95)	0.34	1.55 (1.73)	0.27
Time (Ref: baseline)										
6 months	0.08 (0.12)	0.33	-0.35 (0.16)	**0.03**	-0.14 (0.31)	0.36	2.27 (0.52)	**<0.01**	3.50 (0.64)	**<0.01**
12 months	0.63 (0.12)	**<0.01**	-0.21 (0.15)	0.16	-0.21 (0.13)	0.11	2.14 (0.50)	**<0.01**	3.12 (0.80)	**<0.01**
18 months	0.66 (0.13)	**<0.01**	-0.30 (0.16)	0.06	0.25 (0.35)	0.31	1.30 (0.50)	**0.01**	3.15 (0.93)	**<0.01**
group × time										
EXP vs. TAU at 6th month	4.27 (0.17)	**<0.01**	-7.40 (0.22)	**<0.01**	-3.31 (0.43)	**<0.01**	0.92 (0.70)	0.17	1.02 (0.90)	0.21
EXP vs. TAU at 12th month	4.77 (0.17)	**<0.01**	-7.88 (0.24)	**<0.01**	-3.52 (0.47)	**<0.01**	1.23 (0.62)	0.055	1.40 (0.96)	0.14
EXP vs. TAU at 18th month	4.82 (0.18)	**<0.01**	-7.81 (0.23)	**<0.01**	-3.91 (0.50)	**<0.01**	1.77 (0.73)	**0.02**	1.68 (0.80)	**0.04**
Age	-0.08 (0.70)	0.40	0.09 (0.11)	0.28	0.22 (0.31)	0.31	-0.50 (0.69)	0.31	-0.271 (0.61)	0.66
Sex (Ref: females)	-0.75 (0.70)	0.22	1.50 (0.65)	**0.03**	3.26 (2.54)	0.17	0.13 (0.21)	0.33	3.67 (2.72)	0.16
Charlson index	-0.14 (0.11)	0.18	0.05 (0.35)	0.39	0.50 (0.12)	**<0.01**	-1.82 (1.39)	0.17	-1.61 (1.78)	0.27
Body mass index	-0.12 (0.20)	0.34	0.07 (0.32)	0.39	0.24 (0.31)	0.30	-1.11 (1.21)	0.26	-0.04 (0.87)	0.40
Intercept	16.34 (1.58)	**<0.01**	10.96 (1.79)	**<0.01**	41.88 (6.77)	**<0.01**	33.56 (10.62)	**<0.01**	46.12 (12.96)	**<0.01**
$\hat{\sigma}^2_{st}$ (patients)	5.50 (0.36)	**<0.01**	7.66 (0.51)	**<0.01**	117.04 (7.24)	**<0.01**	43.76 (2.70)	**<0.01**	58.14 (1.98)	**<0.01**

$\hat{\sigma}^2_{sc}$ (centers)	2.21 (0.08)	**<0.01**	3.54 (0.12)	**<0.01**	13.70 (0.46)	**<0.01**	33.43 (1.17)	**<0.01**	17.96 (2.57)	**<0.01**

Note. Ref. = reference group for comparison; TAU = treatment as usual group; EXP = intervention group; BMQ = Beliefs about Medicines Questionnaire; PCS = Physical Component Summary; MCS = Mental Component Summary; $\hat{\sigma}^2_{st}$ = the variance at patient level; $\hat{\sigma}^2_{sc}$ = the variance at center level; SE = standard error.

p values < 0.05 are in **bold**

Electronic Supplementary Material Table S5. Direct and mediated effects of group on medication adherence, quality of life (QoL) and survival rates.

Outcome	Time (months)	Mediator	Coefficient (SE)			
			A. Intervention effect on outcome	B. Intervention effect on mediator	C. Mediator effect on outcome	Mediated effect (=B*C)
Medication adherence	6		3.97 (0.22)**			
		BMQ-Necessity		4.27 (0.17)**	0.32 (0.03)**	1.37 (0.14)**
		BMQ-Concerns		-7.40 (0.22)**	-0.27 (0.02)**	2.00 (0.16)**
		PBC		0.58 (0.05)**	0.66 (0.10)**	0.38 (0.07)**
		Intention		0.61 (0.05)**	0.85 (0.12)**	0.52 (0.08)**
		Self monitoring		0.54 (0.06)**	1.22 (0.11)**	0.66 (0.09)**
		Action planning		0.84 (0.06)**	0.95 (0.10)**	0.80 (0.10)**
		Coping planning		0.85 (0.07)**	0.95 (0.10)**	0.81 (0.11)**
		SRBIA		0.57 (0.05)**	0.22 (0.10)*	0.12 (0.06)*
	12		3.83 (0.23)**			
		BMQ-Necessity		4.77 (0.17)**	0.25 (0.03)**	1.19 (0.15)**
		BMQ-Concerns		-7.88 (0.24)**	-0.29 (0.04)**	2.29 (0.33)**
		PBC		0.57 (0.06)**	0.61 (0.11)**	0.35 (0.07)**
		Intention		0.61 (0.06)**	0.88 (0.11)**	0.54 (0.08)**
		Self monitoring		0.54 (0.06)**	1.20 (0.13)**	0.65 (0.10)**
		Action planning		0.87 (0.07)**	0.98 (0.11)**	0.85 (0.12)**
		Coping planning		0.87 (0.06)**	0.96 (0.09)**	0.83 (0.10)**
		SRBIA		0.47 (0.06)**	0.14 (0.10)	0.06 (0.05)
	18		4.24 (0.26)**			
		BMQ-Necessity		4.82 (0.18)**	0.26 (0.04)**	1.25 (0.20)**
		BMQ-Concerns		-7.81 (0.23)**	-0.31 (0.05)**	2.24 (0.40)**
		PBC		0.61 (0.06)**	0.60 (0.09)**	0.37 (0.06)**
		Intention		0.63 (0.05)**	0.92 (0.14)**	0.58 (0.10)**
		Self monitoring		0.58 (0.06)**	1.32 (0.14)**	0.77 (0.11)**
		Action planning		0.93 (0.07)**	0.96 (0.09)**	0.89 (0.11)**
		Coping planning		0.95 (0.08)**	0.93 (0.12)**	0.88 (0.14)**
		SRBIA		0.50 (0.06)**	0.16 (0.10)	0.10 (0.05)*

PCS	6		0.92 (0.70)			
		Medication adherence		3.97 (0.22)**	0.18 (0.05)**	0.71 (0.20)**
		Pharmacy refill rate		9.82 (0.93)**	0.07 (0.02)**	0.69 (0.21)**
	12		1.23 (0.062)			
		Medication adherence		3.83 (0.23)**	0.160 (0.01)**	0.61 (0.05)**
		Pharmacy refill		10.64 (0.95)**	0.06 (0.02)**	0.64 (0.11)**
	18		1.77 (0.73)*			
		Medication adherence		4.24 (0.26)**	0.102 (0.04)**	0.42 (0.17)*
		Pharmacy refill		10.40 (0.98)**	0.09 (0.03)**	0.94 (0.32)**
MCS	6		1.02 (0.90)			
		Medication adherence		3.97 (0.22)**	0.28 (0.04)**	1.11 (0.17)**
		Pharmacy refill		9.82 (0.93)**	0.05 (0.01)**	0.49 (0.11)**
	12		1.40 (0.96)			
		Medication adherence		3.83 (0.23)**	0.30 (0.06)**	1.15 (0.24)**
		Pharmacy refill		10.64 (0.95)**	0.06 (0.02)**	0.64 (0.22)**
	18		1.68 (0.80)*			
		Medication adherence		4.24 (0.26)**	0.29 (0.05)**	1.23 (0.22)**
		Pharmacy refill		10.40 (0.98)**	0.04 (0.01)**	0.42 (0.11)**
Survival rate	6		1.92 (0.67)**			
		Medication adherence		3.97 (0.22)**	0.06 (0.02)**	0.24 (0.08)**
		Pharmacy refill		9.82 (0.93)**	0.12 (0.04)**	1.18 (0.41)**
	12		2.14 (0.38)**			
		Medication adherence		3.83 (0.23)**	0.08 (0.03)**	0.31 (0.11)**
		Pharmacy refill		10.64 (0.95)**	0.19 (0.03)**	2.02 (0.34)**
	18		2.87 (0.47)**			
		Medication adherence		4.24 (0.26)**	0.07 (0.01)**	0.30 (0.05)**
		Pharmacy refill		10.40 (0.98)**	0.31 (0.11)**	3.22 (1.18)**

BMQ= Beliefs about Medicines Questionnaire; PBC= Perceived behavioral control; SRBIA= Self-report Behavioral Automaticity Index; PCS = Physical Component Summary; MCS = Mental Component Summary; SE = standard error.

*$p < 0.05$; **$p < 0.01$.