A PILOT RANDOMIZED CONTROLLED TRIAL ON MOTIVATIONAL INTERVIEWING IN RETURN TO WORK AFTER WORK DISABILITY

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Abstract

Purpose Does 15-minute consult using Motivational Interviewing (MI) have a positive effect on (1) time until return to work (RTW) and relapse after work resumption for patients who have been work disabled for longer than 3 months, and (2) can psychological variables (i.e., work-related motivation, work-related psychological needs, quality of life and work ability) explain these results?

Methods 265 patients were included in a pilot randomized controlled trial, parallel and single blind, with an allocation ratio of 1:1 comparing the consult with MI with the <u>consult as usual group</u> (CAU). There was a 12-month follow up on actual RTW and relapse for both groups. The psychological outcomes were work-related motivation (MAWS), work-related psychological needs (BPNSFS), quality of life (EQ5D5L)) and work ability (WAI). Measurement of these indicators took place at baseline, 1 week after the intervention and 3 months after the intervention.

Results Patients in the MI group showed faster RTW and had a lower chance of relapse compared to those in <u>the CAU</u> condition. No significant differences were found between MI and CAU for the psychological outcomes.

Conclusions Based on our results, there is some evidence that counseling including MI helps work-disabled patients to RTW faster and experience less relapse. However, much remains unknown about the underlying psychological mechanisms explaining this effect. <u>Suggestions are made for the full RCT.</u>

Keywords

motivational interviewing; return to work; work disability; motivation; self-determination theory

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INTRODUCTION

Work disability has negative implications, both for the work disabled people themselves as well as for organizations and society [1]. People that are disabled from work often suffer from psychosocial problems, financial stress, and social exclusion [2], while organizations face an economic cost. Within the field of work disability and return to work (RTW), the biomedical framework has been dominant. This framework assumes that once the disease is diagnosed and medical treatment is started, patients' conditions are expected to improve so that - in due course - patients can resume their activities (e.g., work). However, a biopsychosocial framing is a more appropriate way of understanding disease and disease-related problems. Both biological as well as psychosocial factors should be taken into account [3] as there is more to disease than biomedical markers alone [4]. Particularly work motivation seems to be an important predictor of RTW, sick leave and early retirement [5, 6].

1. Work motivation

For work motivation to be promoted, physicians need to take a non-authoritarian role, meaning that they take a more collaborative role in which one does not act from an expert role and does not expect the patient merely to follow recommendations. This might be particularly challenging in RTW, as a physician typically takes a more authoritarian, controlling style and focusses most often on vast return to work activities. However, such a style is likely to lead to resistance in the patient, as a patient might not feel understood and - at the worse - is left helpless and out of control of one's own life. In the field of RTW, resistance towards suggestions from the physician is often confused with the absence of motivation. However, patients might feel forced and re-activation may not be the outcome or at least not be successful on the long term [7]. To the contrary, in order for any behavior change to be successfully achieved, motivation literature stresses the importance of building autonomous and not controlled motivation [8 – 10]. Such is the basic premise of Motivational Interviewing (MI) [9].

2. Motivational Interviewing (MI)

The general philosophy of MI is to combine a supportive and directive intervention to increase motivation [11]. Rather than taking an authoritarian role, the physicians or counselors aim to help patients detect ambivalence regarding behavior change and assist them in making informed and contemplated choices [12, 13]. It is important that patients themselves state what they want to change, as people more strongly believe self-statements. MI is based on four guiding principles: expressing empathy, developing discrepancy, rolling with resistance, and supporting self-efficacy. There are four phases in the MI intervention: engaging (forming a working alliance), focusing (defining reintegration goals), evoking (hearing the patient's arguments for reintegration) and planning (initiate or continue reintegration).

MI has already been proven to be effective in several health care contexts including addiction care, eating disorders and therapy compliance [14–16]. Since MI is effective to promote behavioral change, it may be especially beneficial in a RWT context as RTW can be conceptualized as a complex human behavioral change [17, 18]. Even though MI has been widely studied and is considered a flexible intervention strategy, there is little research on its effectiveness to improve RTW outcomes. MI has already proven to be useful in musculoskeletal problems in RTW [20] and in mental illnesses [21, 22],

but research is too often diagnosis-specific, leaving the question as to whether it also helps patients with other diagnosis to formulate a wish to change and overcome the obstacles they experience. A recent review on this topic therefore indicated that more research is needed to determine whether MI can be usefully applied to improve RTW [19]. Moreover, MI is mainly a practical framework that can be applied in different contexts. Research on motivation in the context of work and RTW has been proven to be useful when motivation is framed within the Self-determination Theory (SDT) [6]. We therefore will use SDT as a guiding framework in the current study.

3. Motivational Interviewing and Self-Determination Theory

Despite its original bottom-up emergence, MI's core idea that people need to be motivated themselves to change such that the new behavior is something that they want instead of something they feel obliged to (or something they do to simply obtain an external reward) strongly aligns with SDT's notion of autonomous motivation and the principles on how people can be motivated best according to this theory. Autonomous motivation includes intrinsic motivation (i.e., engaging in an activity because you like the activity itself), identified regulation (i.e., because it is personally useful or important to a person) and integrated regulation (i.e., when the importance of the activity is fully aligned with other core values and beliefs of a person). Controlled motivation consists of external regulation (i.e., doing an activity because one wants to receive a reward from others or avoid punishment) and introjected regulation (i.e., to fuel one's self esteem and feel good or not bad about oneself). When people are controlled motivated, they experience pressure to think, feel, and behave in a certain way. Amotivation refers to a state where people just go through the motions and are not motivated at all. Several studies confirm that – for both employees and unemployed people – autonomous motivation (rather than controlled motivation or amotivation) supports mental wellbeing and professional functioning. It relates for example to more employee job satisfaction, work engagement, organizational commitment, decreased burn-out, better performance and more job search behavior among the unemployed [23, 24]. In the context of RTW, autonomous – but not controlled - motivation is linked to higher quality of life of the work disabled and shorter duration of their work disability [6, 7]. SDT also adds that high autonomous motivation can be facilitated by the satisfaction of three basic psychological needs: the need for autonomy (i.e., feeling psychologically free), relatedness (i.e., feeling connected and cared for), and competence (i.e., feeling effective) [10].

Previous studies (albeit mostly among patients with musculoskeletal disorders) have shown that professional encounters and communication are important factors affecting the motivation for RTW, the self-estimated work ability and the outcome of long-term work disability [25, 26]. On this basis, we presume that a motivational counseling style, based on the principles and philosophy of MI, can positively affect work-disabled patient's RTW, well-being, motivation for work, and quality of life in the long term. We also assume it to be negatively related to patient's reported work disability. Using SDT as a theoretical frame, we also presume the satisfaction of basic psychological needs (autonomy, relatedness, competence) to be the mechanisms leading to these intermediate presumed effects and -in the longer term- to effective behavior change. We therefore also expect motivational counseling to result in a faster RTW and less relapse. In the current study, we conducted a pilot randomized controlled trial (RCT) in which consults based on MI were compared to the consult as usual (CAU) in the context of a social security agency. When work disabled in Belgium, one receives a benefit from social security. A physician or paramedic evaluates the person's right to receive this benefit.

For methodological reasons and the novelty of the study, we first aimed to conduct a pilot study and formulate recommendations based on this to improve MI, based on SDT, in this context [27]. Outcomes are therefore followed up in the mid-long term (up to 6 months after the intervention) so that a larger study can be set up after the pilot RCT. The current study focusses on the outcome evaluation, yet we also try to explain the emergence of these outcomes via the satisfaction of the basic needs. However, parallel to the current RCT a complementary qualitative study is added in which participants were interviewed, for the purpose of process evaluation.

METHODS

1. Trial design

We adopted a simple randomized controlled trial which was parallel and single blind, with an allocation ratio of 1:1. The clinical trial registration number was S62188 (clinical trial center). The research was conducted at the Alliance of Christian Sickness Funds, which is the largest social security funds in Belgium covering approximately 42% of the mandatory insured population. Within this funds, the social security physician and his team of paramedic coworkers have regular contact with the work disabled. Data were abstracted from questionnaires pre- and post-intervention and data from the social security funds regarding RTW and relapse from 27 October 2019 – 30 June 2020. The study was approved by the Ethics Committee Research UZ/KU Leuven (B322201941009).

2. Participants

Participants were recruited via the social security agency between October 2019 and December 2019. All patients receiving a disability benefit were eligible. Patients were excluded in case of cognitive impairment and non-Dutch speakers (since one had to be able to fill in the questionnaires independently) or being unavailable for the labor market due to pregnancy or being aged under 18 or older than 65. By default, the social security funds provides a physician or paramedic's consultation with people on work disability 3 to 6 months after the onset of the sickness period. The goal of this consultation is (1) to gather information on the reason of work disability and the treatment plan, (2) evaluate the right to receive an imbursement and (3) to encourage people to RTW.

On average, participants were invited at the physician or paramedic's consultation after 3 to 6 months of work disability. An administrative assistant of the social security funds gave a questionnaire to the work disabled person who signed in for the consultation. Participants could thus complete the questionnaire in the waiting room. The questionnaire was preceded by an informational letter and the informed consent. They were asked to read and complete the informed consent and had the opportunity to complete the questionnaire after consenting. Patients were informed that the consultation style of the physician or paramedic was subject to a research project but did not receive information on whether or not the physician or paramedic used the MI counseling style. Participants were then filtered out by the researchers based on the exclusion criteria. Participating physicians and paramedics were informed in advance that a study was running but were not aware if their patients enrolled in the study. Questionnaire data were coded such that participant code and data could only be linked by the first author.

3. Description of interventions

a. Motivational Interviewing (MI)

The motivational interviewing (MI) intervention involves a single conversation initiated by the social security paramedic (i.e., MI practitioner) about behavioral change in terms of recovery or RTW of the work disabled person. The MI intervention was performed by 1 paramedic (female, 28 years old, psychologist). She was trained in MI through certified training. The MI intervention focuses primarily on one of the 4 stages of MI: engaging (working alliance), focusing (defining reintegration goals), evoking (patient voice arguments for reintegration) and planning (initiate or continue reintegration). The aim was to evoke change talk on behalf of the patient, who then expresses a desire, a reason, an ability or a need for change (i.e. regarding the process of RTW). In this interview, the same information was to be gathered as in the CAU. A time slot of 20 minutes was allocated for each single session. The content of the conversation depended on the stage of readiness of the participant as evaluated based upon clinical experience of the counselor. With patients who still had a lot of resistance, the first stage was taken, i.e. engaging, and only when they were ready, focusing and evoking. If a participant was ready to take steps towards work, the 4th stage, i.e. planning, could be faced quite quickly.

b. Consult as Usual (CAU)

A total of 3 social security physicians (male, 60 years; female, 48; female 54) and 5 paramedic coworkers (male, 54, nurse; female, 60, nurse; female, 40, physical therapist; female, 35, physical therapist; male, 30, occupational therapist) provided the CAU, in which the work disabled received the same normal consult as in the MI, but without the motivational interviewing. There were no additional guidelines for the CAU and none of these health care workers were informed about MI. In a CAU, information is gathered about the medical condition, the course of the work disability process, the steps towards work, and an evaluation of whether this person meets the criteria for remaining work disabled. It is assumed that the CAU has a more authoritarian consultation style.

4. Outcomes

Data on diagnoses (ICD group), age, sex and education were extracted from the data of the Social security funds. Being returned to work and being relapsed were primary outcomes. Basic psychological needs, motivation, work ability and quality of life were intermediate outcomes.

a. Basic psychological needs

The Basic Psychological Needs Satisfaction and Frustration Scale (BPNSFS)[29] was used to assess the satisfaction and frustration of the basic psychological needs for autonomy, competence and relatedness. Responses were made on a five-point scale from 1 (strongly disagree) to 5 (totally agree). Need satisfaction was measured by summing up the subscales of autonomy satisfaction (e.g. I feel my choices express who I really am), relatedness satisfaction (e.g. I feel that the people I care about also care about me) and competence satisfaction (e.g. I feel capable at what I do). Need frustration was measured by summing up the subscales of autonomy frustration (e.g. my daily activities feel like a chain of obligations), relatedness frustration (e.g. I feel the relationships I have are just superficial) and competence frustration (e.g. I feel insecure about my abilities). The BPNSFS was measured at

baseline, 1 week and 3 months after the intervention. The internal consistency ranged from 0.80 to 0.93 across measuring points.

b. Motivation

The Motivation at work scale (MAWS)[28] was used to measure amotivation as well as controlled and autonomous motivation. Participants were asked about their motivation for their latest job (before their work disability). Responses were made on a 7-point scale from 1 (strongly disagree) to 7 (totally agree). Controlled motivation was measured by taking the average of the subscales of external (e.g. so that I don't get fired) and introjected (e.g. otherwise I would feel bad about myself) motivation. Autonomous motivation was measured by taking the average of identified (e.g. I personally believe it's important to put effort into my work) and intrinsic (e.g. because I have fun at work) motivation. Amotivation (e.g. I feel like I'm wasting my time in this job) was rated as a separate scale. Motivation was measured at baseline and 3 months after the intervention. We do not expect motivation for work would change to such an extent after 1 week, since conversational techniques take time to be processed [46]. The internal consistency was 0.68 at baseline and 0.78 three months later for controlled motivation, 0.88 to 0.91, respectively for autonomous motivation and 0.78 to 0.85 for amotivation across measuring points.

c. Work ability

We used the single-item question on work ability [29]: "current work ability compared with the lifetime best", with a possible score of 0 ("completely unable to work") to 10 ("work ability at its best"). This item is very strongly associated with the Work Ability Index (WAI; 10 items). Work ability was measured at baseline, 1 week and 3 months after the intervention.

d. Quality of life

Quality of life (QOL) was measured by the EQ-5D-5L [30]. The EQ-5D is the most well-known and commonly used generic measure of health status. The EQ-5D-5L is a brief self-reported questionnaire on current health and consists of 5 dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression). Each of the dimensions has 3 levels of functioning: no problems, some problems, and unable to/extreme problems. QOL was measured at baseline and 3 months after the intervention. QOL is a less rapidly changing concept and therefore was not yet measured after one week.

e. Return to Work

The duration of work disability was retrieved from the administrative of the social security funds. RTW was defined as no longer being registered on sickness benefits, either full-time or part-time. There was a follow-up for 12 months after the onset of work disability.

f. Relapse

Relapse in work disability within a year was retrieved from the administrative of the social security agency. Being relapsed was defined as again being registered on sickness benefits either full-time or part-time. The incidence of relapse was follow-up for a 12 month-period after the onset of work disability.

5. Sample Size

In order to achieve sufficient power (α =.05, β =.20) with an incidence of p=0.05 for the intervention group and p=0.20 for the CAU, we aimed at 150 participants per group. Enrollment was stopped within the foreseen timeframe of October – December 2019.

6. Randomization

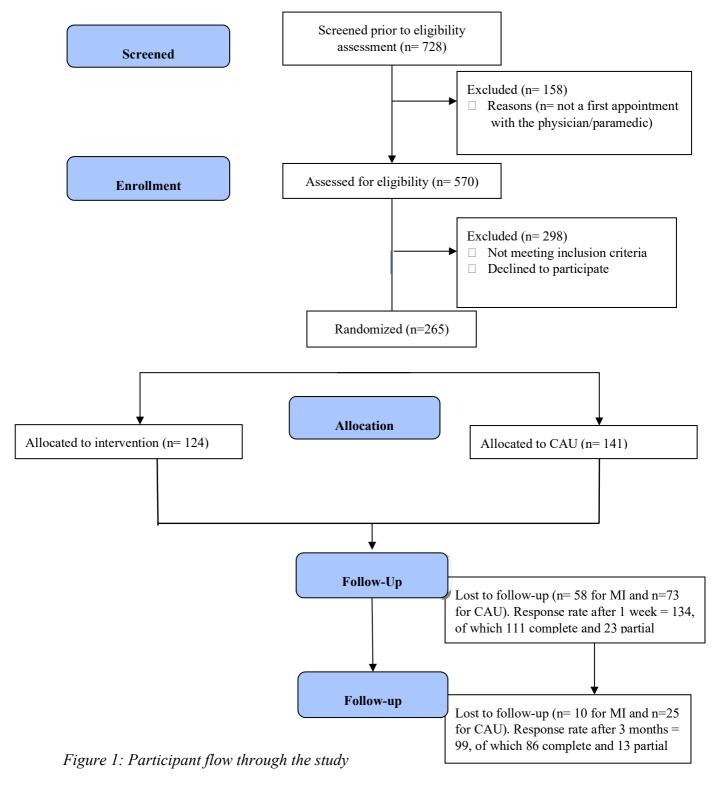
Patients were randomized by a computer system of the social security <u>funds</u>. This system assigns patients to a social security physician or paramedic coworker for their consultation to evaluate their work disability. This system does not take into account pathology, age, previous periods of illness, or other variables, but simply fills the agenda randomly according to the availability of the physician or paramedic. The allocation is definitive, and the researchers were not able to influence the process. The randomization rate for the intervention and control group was set at 1:1 in order to have equal samples. The patients were blinded for the randomization, the interventionists were not.

7. Statistical methods

Prior to our (main) analyses, the impact of dropouts (68%) was explored by fitting a binary logistic regression model to the data. Missing (coded as 1 = missing, 0 = non-missing) was defined as dependent variable, while the factors RCT (MI vs CAU), education, ICD group, RTW, amotivation, controlled motivation, autonomous motivation, basic psychological need satisfaction and need frustration, work ability and quality of life, were defined as predictors. Results reveal a significant effect of RTW (χ 2(1)=4.18, p = 0.041). Participant who did RTW are more likely to fill in the questionnaires at 3-month follow up (estimated probability of 58%, 95CI=[47%-69%]) compared to participants who did not RTW (estimated probability of 75%, 95CI=[64%-84%]). Both samples (missing and non-missing) did not differ with respect to the other variables. Lee and Shi [31] recently argued that full information maximum likelihood and multiple imputation – two missing data procedures- seem to yield equivalent results. Therefore, we chose to use the full information maximum likelihood procedure to deal with the missing values.

To investigate the impact of the intervention, *linear mixed effects models* were fit to the data by using the R package "lme-4" [32]. For each model the (fixed) factors time and RCT (MI vs CAU) were considered as effect-coded fixed factors while participants were defined as a random-effect factor. For each dependent variable, two nested models were considered: a 'basic' model with time, RCT and the two-way interaction between time and RCT and a more extensive model. This model extended the basic model by adding the control variables (education, ICD group, RTW) as effect-coded fixed factors. Also, the two-way interactions between control variables and time and between control variables and RCT were added. Finally, the three- way interactions between control variables, time and RTW were also defined into the model. The p-values for fixed effects are based on a Type III ANOVA using a $\chi 2$ -distribution as implemented in the R package "car"[35]. Significant effects are

described by means of fitted values and 95% confidence intervals as described in the R packages "effects" [35]. To control for type-1 errors, alpha is set to .05 prior to all analyses. Linear mixed effect models were used to measure the effects of the intervention on motivation, the basic psychological needs, quality of life and work ability. A *Kaplan-Meier analysis* was used to measure the effect of the intervention on the chance of RTW and the chance of a relapse. The Kaplan-Meier test was analyzed using SPSS version 26.0, Chicago, IL, USA.



RESULTS

1. Baseline data

a. Demographic and clinical characteristics

Baseline demographic and clinical characteristics for each group are presented in Table 1.

N 141 124 Age 44.91 (13.21) 44.81 (12.44) Sex Male 64 47 Female 77 78 ICD 10 group V 49 49 VI 1 0 0 VIII 0 1 1 IX 3 1 1 X 1 0 1 XII 3 0 0 XIII 59 46 4 XVI 0 1 1 XVIII 4 2 2 XIX 11 13 1 Chronic fatigue 10 12 12 Education 37 49 49 High school 43 26 26 Bachelor 28 25 25 Master 12 8 Days WDintervention 184.35 (175.95) 161.04(65.75) Amotivation 2.26 (1.41) 2.16 (1.45) Controlled motivation 4.97 (1.34) 4.84 (1.45)		CAU	MI
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Controlled motivation 4.97 (1.34) 4.84 (1.45)	DaysWDintervention	184.35 (175.95)	161.04(65.75)
,	Amotivation	2.26 (1.41)	2.16 (1.45)
Autonomous motivation 5.50 (1.26) 5.60 (1.05)	Controlled motivation	4.97 (1.34)	4.84 (1.45)
	Autonomous motivation	5.50 (1.26)	5.60 (1.05)
BPNS 3.96 (0.76) 4.00 (0.70)	BPNS	3.96 (0.76)	4.00 (0.70)
BPNF 2.24 (0.88) 2.24 (0.88)	BPNF	2.24 (0.88)	2.24 (0.88)
QOL 10.04 (3.25) 11.04 (2.56)	QOL	10.04 (3.25)	11.04 (2.56)

Table 1. Baseline demographic and clinical characteristics for each group.

DaysWDintervention = the number of days on work disability at baseline; BPNS = basic psychological need satisfaction; BPNF = basic psychological need frustration.

Diagnoses were prescribed by a physician of the curative sector, based on the ICD-10 (International Classification of Diseases version 10): 59 % of the participants were on sick leave because of a mental illness (ICD 10 V), 48.5 % had a musculoskeletal condition (ICD 10 XIII and XIX), 8.3% had a chronic fatigue or chronic pain condition, 2.3% had deviant laboratory results (ICD 10 XVIII), 1.5% had a disease of the circulatory system (ICD 10 IX), 0.4% had a neurologic condition (ICD 10 VI) and 0.4% had a disease of the respiratory system (ICD 10 X). Only diagnosis with code V, XIII, XIX and chronic fatigue or chronic pain condition were withheld, and other diagnoses were grouped in a category 'other' for the following analyses. Education was divided into 5 groups: no education, professional training, technical training, secondary school education, higher education and university. CAU en MI did not statistically differ on these variables.

2. Participant flow

The participant flow can be found in figure 1.

3. Outcomes

a. Kaplan-Meier: RTW and Relapse

Return to Work. Results of the impact of the intervention on the duration before RTW can be found in table 2. The Log Rank test (Mantel-Cox) of the two curves yields $\chi 2 = 4.09$, p < 0.04. The MI condition results in a chance of faster RTW compared to the CAU. Figure 2 displays the instantaneous chance that the patient will RTW in both condition MI and CAU.

	Mean (SD)	CI	
Return to Work			
MI	294.76 (7.85)	279.38 - 310.14	
CAU	311.34 (6.81)	298.00 - 324.69	
Relapse			
MI	75.17 (8.50)	58.50 - 81.83	
CAU	34.44 (8.29)	18.19 - 50.70	

Table 2: Means for survival time of the MI and CAU condition for RTW and relapse expressed in days before RTW or days before relapse after RTW

Relapse. Results of the intervention on relapse in work disability can be found in table 2. The Log Rank test (Mantel-Cox) of the two curves yields $\chi 2 = 5.01$, p < 0.025. The MI condition results in a chance of less relapse compared to the CAU. Figure 3 displays the instantaneous chance that the patient relapse in both condition MI and CAU.

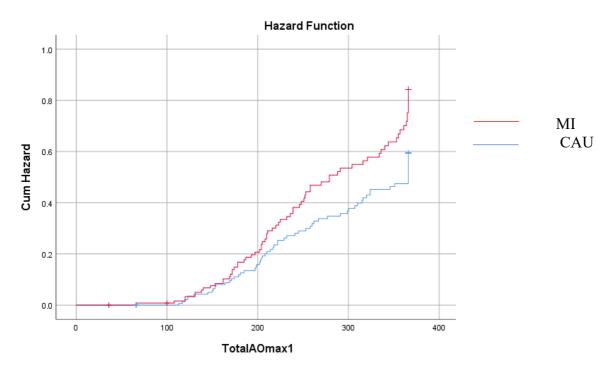


Figure 2. The hazard function graph on the instantaneous chance that the patient will return to work in both condition MI and CAU. The x-axis represents the number of consecutive work disabled days. The y-axis represents the cumulative hazard.

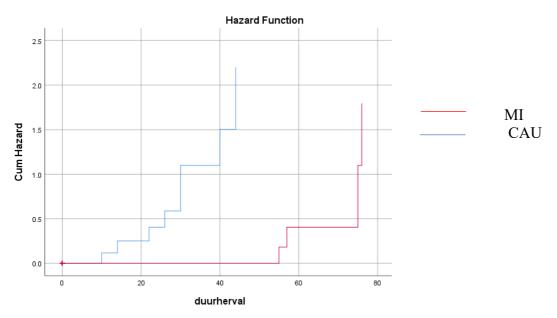


Figure 3. The instantaneous chance that the patient relapse in both the MI intervention and the CAU. The x-axis represents the number of days between two sickness periods. The y-axis represents the cumulative hazard.

b. Mixed linear models

Autonomous motivation. The basic model revealed a significant main-effect of time ($\chi 2(1)$ =34.36, p < .001). It seems that the autonomous motivation score (5.53, 95CI=[5.38-5,68]) at baseline is higher compared to the score after 3 months (4.95, 95CI=[4.74-5.16]). Neither the main effect of RCT ($\chi 2(1)$ < 1) nor the interaction effect between time and RCT ($\chi 2(1)$ < 1) was significant. The extended model showed significant main effects of time ($\chi 2(1)$ =17.10, p < .001) and ICD group ($\chi 2(4)$ =12.06, p < .017). Fitted values reveal a higher autonomous motivation score for the ICD 10 XIII group (musculoskeletal) and a lower score for the ICD10 V group (mental illnesses) (aggregated over time and RCT).

Controlled motivation. The basic model revealed a significant main-effect of time ($\chi 2(1)=52.58$, p < .001). It seems that the controlled motivation score (4.90, 95CI=[4.73-5.08]) at baseline is higher compared to the score after 3 months (3.77, 95CI=[3.49-4.05]). Neither the main effect of RCT ($\chi 2(1)$ < 1) nor the interaction effect between time and RCT ($\chi 2(1)$ < 1) was significant.

Amotivation. The basic model revealed a significant main-effect of time ($\chi 2(1)=54.39$, p < .05). It seems that the amotivation score (2.23, 95CI=[2.94-2.41]) at baseline is lower compared to the score after 3 months (2.52, 95CI=[2.24-2.80]). Neither the main effect of RCT ($\chi 2(1) < 1$) nor the (crucial) interaction effect between time and RCT ($\chi 2(1) < 1$) was significant. The extended model showed significant main effects of ICD group ($\chi 2(4)=16.14$, p < .003) and interaction between the RCT condition (MI vs CAU) and ICD group ($\chi 2(4)=11.18$, p < .024. Fitted values reveal an amotivation increase for MI in case of mental disorders (ICD 10 V) or musculoskeletal disorders (ICD 10 XIII and XIX) and no significant effect for chronic fatigue or the rest group.

Basic psychological need satisfaction (BPNS). The basic model revealed a significant main-effect of time ($\chi 2(2)=11.62$, p < .01). It seems that the BPNS at baseline (3.77, 95CI=[3.89-4.07]) is lower compared to the motivation score after 1 week (3.81, 95CI=[3.70 - 3.93]) or 3 months (3.81, 95CI=[3.68-3.95]). Neither the main effect of RCT ($\chi 2(1) < 1$) nor the interaction effect between time and RCT ($\chi 2(1) < 1$) was significant. The extended model showed significant main effects of education ($\chi 2(5)=11.21$, p < .05) and ICD group ($\chi 2(4)=23.29$, p < .001). Fitted values reveal a lower BPNS for participants with a secondary school education compared to other educational groups and lower for mental disorders.

Basic psychological need frustration (BPNF). The basic model revealed a significant main-effect of time (χ 2(2)=7.21, p < .03). It seems that the BPNF at baseline (2.25, 95CI=[2.14-2.36]) is lower compared to the motivation score after 1 week (2.35, 95CI=[2.21-2.49]) or 3 months (2.44, 95CI=[2.28-2.60]). Neither the main effect of RCT (χ 2(1) < 1) nor the interaction effect between time and RCT (χ 2(1) < 1) was significant. The extended model showed significant main effects of education (χ 2(5)=17.24, p < .004) and ICD group (χ 2(4)=26.52, p < .001) as well as an interaction between the intervention (RCT: MI vs CAU) and ICD group (χ 2(4)=13.17, p < .01). The BPNF in the CAU group is lower compared to the MI group in case of chronic fatigue. BPNF is higher compared to the MI group in case of musculoskeletal disorders.

Work ability (WA). The basic model revealed a significant main-effect of time (χ 2(2)=10.38, p < .006). It seems that the WA at baseline (4.20, 95CI=[3.93-4.48]) is lower compared to the score after 1 week (4.37, 95CI=[3.98-4.76]) and 3 months (5.22, 95CI=[4.77-5.67]).

Quality of life: No main effects of time or RCT, nor an interaction effect was found for quality of life.

DISCUSSION

In this pilot RCT, MI resulted in less relapse and a faster RTW. On average, participants returned to work 17 days faster in the MI intervention compared to the CAU. People in the MI intervention relapsed nearly two times later compared to the CAU. No differences were found between MI and CAU for the psychological variables of work-related motivation, basic psychological needs, work ability and quality of life.

MI thus shows promising outcomes in terms of RTW, but not in the underlying psychological factors. This is different from previous research where the effect of other interventions on symptom levels (e.g. feeling better, less depressive symptoms) is often more successful than the effect on RTW [36]. This could be due to the fact that MI is especially useful for people who are less motivated and are not yet ready to change their behavior. For these patients, interventions focused on action can result in adverse results for their motivational levels.

In addition, psychological variables might be measured too generally. E.g. need satisfaction was measured in general, not in relation to the consultant, and therefore possibly not measured specifically enough to explain the process. The same generality applies to the other psychological variables. In addition, our study was **underpowered to detect small and medium effects.**

Another possible explanation for the lack of significant results on the psychological factors, could be that a one-time MI would not be sufficient to change motivation. It could, for example, be possible that MI is only or especially useful on top of another treatment (e.g. cognitive therapy, occupational rehabilitation). Previous research already indicated that motivation seems to be a facilitator for the successful implementation of RTW programs [36, 37]. In addition, motivation should not only be a focus at one point in the RTW process, but it should be maintained throughout the process [37]. Deci and colleagues recommend that positive and lasting results in RTW most likely occur when a patient is motivated, actively engaged, and invested in change. We therefore suggest that the intervention should be offered more than once in the final RCT. **Also**, motivation is measured in relation to the job previous to the work disability. It is unclear weather participants were still with the same employer at the moment of data collection. This variable will be taken into account in the major RCT. Lastly, we suggest to conduct exit interviews with participants in the final RCT to rule out whether participants, despite MI's good intentions, still felt pressured given the context.

The results regarding the psychological variables merit some more discussion. First, self-efficacy is considered to be one of the most important factors for RTW after 6 months [38] and was not included in the study because of its supposed overlap with the need for competence (SDT). Also, other studies could not establish an effect of an MI intervention on self-efficacy [36] and a longitudinal study by Labriola et al. [39] exploring the impact of self-efficacy on RTW in a large sample of Danish workers did not find the expected relationship either. One reason for the lack of these unexpected findings may be the use of a general self-efficacy scale instead of the RTW – self-efficacy sale (RTWSE)[40]. The RTWSE is defined as the belief in the capacity to meet the demands required for RTW and would be more suitable. In the major RCT, the RTWSE will be added as variable.

Second, it is noteworthy that work-related motivation – both autonomous and controlled – declined over time, whereas amotivation remained stable. It is widely acknowledged that the longer an employee is off work, the smaller his chances of ever returning to work. For this reason, early intervention is key. Yet, RTW is not merely a state. It is a multi-phase process, including a series of events and phases as well as interactions with the environment [41]. It should therefore be recognized that, due to the complexity of RTW, insurance professionals alone cannot tackle the multiple obstacles for an employee's RTW to the workplace. Improving RTW requires the efforts of patients and their families, healthcare providers, healthcare authorities and employers [43]. It must be noted however, that motivation in the current study was measured regarding the previous employer. Motivation towards finding a new job, general recovery, retraining, rehabilitation etc. was not included in the current study, but will be measured in the major RCT.

Third, basic psychological need satisfaction also declined over time, regardless whether the work disabled took part in the MI or CAU. The satisfaction and frustration of psychological needs was measured with regard to the general life context and therefore might be too general in terms of the current research. In addition, due to the registration system of work disability in Belgium, we could not take into account whether patients already partially resumed work throughout the study or not. In the major RCT, we will therefore ask at the various measuring moments whether participants have already partially returned to work, and whether this is with the same employer or after job turnover. Finally, there are some findings regarding diagnosis. People with a musculoskeletal disorder reported higher autonomous motivation, and higher basic needs satisfaction. The score for autonomous motivation in case of mental illnesses declined over time. The latter is in line with other research, where less autonomous motivation was related to poorer mental health [44]. This could, however, have vast implications for the RTW of both groups.

Participants with chronic fatigue in the current research reported more frustration of the basic needs in the CAU group compared to the MI group. Although the sample size is insufficient to make such strong claims, it does raise the question whether the intervention may be particularly relevant among certain diagnostic groups.

Study strengths and limitations

The use of a randomization and parallel design is a strength of the current study. Randomization appeared adequate. Data were gathered in an actual setting, not an experimental setting and the results are therefore ecologically valid. The competency of the MI-interventionist was verified trough recording and coding. The study included patients with all different types of diagnoses, which allowed to test whether the MI intervention leads to generalizable results. The current study focusses on the outcome evaluation, yet we also try to explain the emergence of these outcomes via the satisfaction of the basic needs. However, parallel to the current RCT a complementary qualitative study is added in which participants were interviewed, for the purpose of process evaluation. The results of this study will be presented, whenever available. In all, this pilot RCT provided useful information for a larger follow-up study.

The study also has some limitations. The attrition rate is high despite the measures taken and might be a major source of bias to the study results. There might be several reasons for this. First, there were originally many individuals included in the administrative process who did not show up or who were excluded by us based on the exclusion criteria. The largest dropout is in this phase (see Figure 1) and should be addressed in the final RCT. It should be noted that the dropout between waves is random (as

it is also equally distributed between both groups). Second, it may be that participants prefer to be confronted as little as possible with the medical control mechanism to which they link the study because it may bring anxious or negative feelings. Third, while the first assessment point occurred in the waiting room before the consultation, later assessment points took place at home. This may have increased drop-out at later time points since these possibly had to be completed at more inconvenient times (e.g., during the day) and might have been forgotten or perceived to be of lesser importance. The fact that assessment at later assessment points was to be provided digitally possibly lowered attrition rates, but not to a significant extent. A third important observation is that the first questionnaire was paper based, the second and third digital. Overall, drop out was 49% at time 1 and another 10% at time 2. This attrition rate can cause links in the study to be over identified. However, such numbers are comparable to other studies [45] and drop-out was taken into account in the data analysis. In any case, it is important to implement strategies in further studies aimed to diminish attrition rates the best as possible, also to prevent selective drop-out to occur. As a second limitation, there's an imbalance between the number of interventionists in the intervention group (1) and the control group (6). As a result, we cannot strictly distinguish MI and one person's effect. A larger number of MI interventionists should be addressed in the full trial. This requires training and verification of the training-effect. Furthermore, difference in a MI-style between intervention trial and CAU should be examined, as additional validation of training. Third, although the MI-adherence of the MI-interventionist was evaluated, it was not examined whether the (para-) medics in the CAU did not use (aspects of) MI. However, the (para-)medics in the CAU were unaware of the existence of MI or haven't had any training in MI. A treatment fidelity check will be performed in the full trial. Fourth, there was unexpectedly no association found between the psychological variables and MI condition. This is expected in the final RCT, however. Fifth, the study could not be double blinded since the intervention was inherently linked to the interventionist.

Practical implications

The use of brief MI within a context of work disability as a conversation style can contribute to a faster RTW and less relapse. It is suggested that repeated brief MI is preferable to a single session. The importance of early intervention is underlined.

Conclusion

MI seems effective in the context of RTW in terms of less relapse and a tendency towards a faster RTW. However, underlying or intermediate factors remain unclear. The current pilot RCT was exploratory in nature and provides essential insights for the final RCT. The intervention should be implemented more than once, outcome variables should be more customized and possible similarities between the interventions need to be filtered.

Trial Registration

The study protocol was registered at the Clinical Trial Centre (CTC) with code S62188

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