ISRCTN05534684 https://doi.org/10.1186/ISRCTN05534684

Improving the diagnostic procedure for injured patients - Optimization for the questionnaire "Fragebogen Arbeit und Befinden" (OptiFAB) [Diagnostik der Unfallbetroffenen der Suva]

Submission date
18/08/2011

Recruitment status
No longer recruiting

Registration date
08/12/2011

Overall study status
Completed

Last Edited
11/07/2017

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The aim of the study is to improve the treatment (triage) and the diagnostic procedure for insured people with disabilities (e.g. in the mental health or work related area) after an accident.

Who can participate?
Insured people with disabilities (e.g. in the mental health or work related area) eight weeks after an accident, aged at least 18

What does the study involve?
Participants are randomly allocated to either the intervention group or the control group. The intervention is a psychological intervention and/or work related intervention based on the principles of cognitive behavioral therapy. Participants in the intervention group receive individual treatment depending on their disabilities or mental health. Participants in the control group receive treatment as usual. In addition there is a third minimal intervention group. In this group randomly allocated case managers follow a standardized manual to improve the triage of the procedure of the diagnostic process. The intervention and control groups are compared in terms of well-being, work-related satisfaction, and return to the workplace.

What are the possible benefits and risks of participating?
The benefit of participation is the free of charge intervention. There are no possible risks of participation.

Where is the study run from?
University of Bern (Switzerland)

When is the study starting and how long is it expected to run for?
September 2011 to December 2013

Who is funding the study?
SUVA (Switzerland)

Who is the main contact?
Prof. Hansjörg Znoj
hansjoerg.znoj@psy.unibe.ch

Contact information

Type(s)
Scientific

Contact name
Prof Hansjörg Znoj

Contact details
Institute of Psychology
Department of Clinical Psychology and Psychotherapy
University of Bern
Gesellschaftsstrasse 49
Bern
Switzerland
3012
+41 (0)31 631 45 91
hansjoerg.znoj@psy.unibe.ch

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
OptiFAB

Study information

Scientific Title
Improving the diagnostic procedure for injured patients: a randomised controlled trial

Acronym
OptiFAB

Study objectives
1. A significant difference in psychological and work-related outcome is expected between groups (OptiFAB and FABpur). Specifically, it is assumed that the group with the psychological and/or work-related intervention will have better outcomes in terms of psychological functioning (well-being) and a faster reintegration into the workplace.

2. A difference in term of a better triage is expected between groups (FABplus and FABpur). As above, it is assumed that the group with a GAS training and a manual will have better and faster triage process.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Philosophical - Human Sciences Faculty Ethics Commission of Bern (Switzerland), 08/06/2011, ref: 2011-04-172

Study design
Blinded randomized experimental intervention study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet [in German]

Health condition(s) or problem(s) studied
Different disabilities after an accident in the area workplace and/or mental health

Interventions
OptiFAB: Psychological intervention or / and work related intervention and Control group
Treatment arm OptiFAB: The intervention consists of 10-20 weekly sessions: structured setting and a combination of educational and supportive coaching elements.
FABplus: Improvement of triage process. A group of case manager receives a "Goal attainment Scale" training and a manual (summarized "the good practice" to faster the triage process)

FABpur: Treatment as usual

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Psychological well-being, measured using BFW/E (Berner Fragebogen zum Wohlbefinden, Grob et al., 1991; 39 Items) 8 weeks after the accident

2. Work-related satisfaction, measured using general job satisfaction (Baillod & Semmer, 1994, 4 Items) 8 weeks after the accident
3. Return to the workplace

Secondary outcome measures
1. Psychosocial conditions and health, measured using:
1.1. Subjective Happiness Scale (SHS, Lyubomirsky & Lepper, 1999, 4 Items)]
1.2. Social support (SALSA, Skala zur Erfassung der sozialen Unterstützung am Arbeitsplatz, IRES-3)
1.3. Fear-Avoidance Beliefs questionnaire (FABQ-d, Staerkle et al, 2004, 16 Items)
2. Coping, self-efficacy, optimism, measured using:
2.1. CISS (short version, Kälin, 2003, 19 Items)
2.2. SWE (Selbstwirksamkeit, Schwarzer, 1993, 10Items)
2.3. LOT-R (Optimism, Glaesmer & Hoyer, 2003, 10 Items)
Data collected 8 weeks after the accident

Overall study start date
01/09/2011

Completion date
31/12/2013

Eligibility

Key inclusion criteria
Patients 8 weeks after an accident have to fullfil followed criteria:
1. Approved accident or occupational disease
2. Unlimited employment contract
3. There must be at least 90 days or more between accident data and employment date
4. NCM-Code > 1
5. Present inability to work
6. No unemployment
7. No full working capacity in the next two weeks
8. Identified as a potential complex case by the questionnaire Arbeit und Befinden (FAB)
9. Able to speak German

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
For each group 100 participants and a total of 400 participants

Key exclusion criteria

1. Inability to communicate or lack of language skills
2. Limited employment contract
3. Between accident data and employment date are less than 90 days
4. NCM-Code < 1
5. Ability to work
6. Unemployment
7. Full working capacity in the next two weeks
8. No complex case
9. Under 18 years of age
10. Not willing to participate in the study

Date of first enrolment
01/09/2011

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
Switzerland

Study participating centre
University of Bern
Bern
Switzerland
3012

Sponsor information

Organisation
SUVA (Switzerland)

Sponsor details
Postfach
Fluhmattstrasse 1
Luzern
Switzerland
6002
-
vmd.bereich@suva.ch

Sponsor type
Government

Website
http://www.suva.ch/english/

ROR
https://ror.org/01t56m506

Funder(s)

Funder type
Government

Funder Name
SUVA (Switzerland)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration