The Danish National Return To Work program (Det store TTA-projekt): a study in 22 municipalities of a return to work program aiming to reduce the duration of sickness absence and to enable earlier return to work for citizens on long-term sick leave

Submission date	Recruitment status No longer recruiting	Prospectively registered		
04/02/2011		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
31/03/2011	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
20/09/2016	Other			

Plain English summary of protocol

Background and study aims

People on long-term sickness absence have an increased risk of losing their jobs and being excluded from the labour market. Many of these people need help to get out of this situation, so that they can continue to enjoy a meaningful life at work.

The Danish National RTW-program includes three approaches that have been shown to have positive effect on return to work (RTW) for people on sickness absence:

- 1. Assessment of barriers and resources for returning to work
- 2. Increased coordination between worker, workplace, health care and social insurance systems
- 3. Early initiation of RTW-activities (counselling, education, on-the-job-training etc.) The aims of the study are:

To improve municipal sickness benefit management

To evaluate the implementation process both from the beneficiaries, the RTW-teams and the external stakeholders point of views

The economic burden of this approach compared to normal sickness benefit management The effects on the participants sickness absence duration, sustainability of RTW and on a range of secondary outcomes (sleep pattern, general health, workability etc.)

Who can participate?

Working-age adults on long-term sickness absence (at least four weeks).

What does the study involve?

The 22 municipalities involved in the project established RTW-teams comprising an RTW-coordinator (typically an experienced social worker who received extensive training), a psychologist and a physiotherapist/occupational therapist. The RTW teams established close

links with psychiatrists and medical doctors. The RTW-coordinators then became the focal point for coordination between the relevant stakeholders, including employers, health care services, unions and unemployment funds and the RTW-team and the clinical unit. Data for the evaluation was obtained by questionnaires, focus-group interviews, individual interviews, municipal data and national register-data.

What are the possible benefits and risks of participating?

These improvements will hopefully reduce the average duration of sickness absence, provide a faster and more sustainable RTW and a positive development in health, sleep and workability for the participants. There are no known risks associated with taking part in this study.

Where is the study run from? National Research Centre for the Working Environment, Copenhagen, Denmark

When is the study starting and how long is it expected to run for? April 2010 to March 2012

Who is funding the study?
The Danish Prevention Fund and the Danish Ministry of Employment

Who is the main contact?
Dr Otto Mechior Poulsen
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Study website

http://www.arbejdsmiljoforskning.dk/da/projekter/det-store-tta-projekt

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Study information

Scientific Title

The Danish National RTW program: a stratified cluster controlled study of a coordinated and multidisciplinary return to work program in 22 municipalities aiming to reduce the duration of sickness absence and to enable earlier return to work for citizens on long-term sick leave

Study objectives

The overall objective of the intervention is to promote return to work (RTW) for citizens on long-term sick leave. The main hypothesis is that a coordinated and multidisciplinary RTW-program reduces the duration of sickness absence and promotes a faster and more sustainable RTW compared to standard municipal case management.

Specific hypotheses are that the intervention group:

- 1. Has a shorter duration of sickness absence
- 2. Is less likely to experience recurrent long-term sickness absence
- 3. Returns to work (become self-supporting) faster
- 4. Reports a more positive development in self-rated health, mental- and physical health, workability, pain and sleep patterns, and
- 5. The coordinated and multidisciplinary RTW-program is more cost-effective than standard municipal case management

Ethics approval required

Old ethics approval format

Ethics approval(s)

The data collection is registered at the Danish Data Protection Agency (www.datatilsynet.dk, ref: 2009-54-08).

The Danish National Committee on Biomedical Research Ethics has in writing confirmed that the intervention does not need their approval. According to the Danish Law, only projects using biological material need approval from the Danish National Committee on Biomedical Research Ethics (http://www.cvk.im.dk/site.aspx?p=513).

Study design

Stratified cluster controlled study

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a participant information sheet

Health condition(s) or problem(s) studied

Long-term sickness absence

Interventions

Current interventions as of 14/09/2011:

The municipalities were assigned to the control and intervention group using a stratified allocation procedure. The initial selection of municipalities was based on applications from 45 municipalities. All applications were assessed for quality and feasibility of implementation plans resulting in a total of 33 municipalities. Further, two municipalities were selected a prior due to the possibility of strong study designs (randomization of individuals and cluster allocation of sickness benefit offices within the sickness benefit offices).

All municipalities were grouped in distinct strata based on their size, socio-economic profile and organisation of the RTW-programme. Finally a stratified cluster selection was performed resulting in 13 municipalities in the intervention group and 9 municipalities (representing 12 offices) in the control group. All control municipalities were offered the intervention after the end of the study. After one year the control municipalities became intervention municipalities. Three of the municipalities are also part of an individual RCT-study (see www.controlled-trials. com/ISRCTN43004323).

The RTW-programme combines a RTW coordinator approach with a multidisciplinary approach. Four of the main strategies of the programme are:

- 1. Early and regular contact with citizens on sick leave
- 2. Multidisciplinary assessment of sick-listed citizens
- 3. Improved coordination between relevant stakeholders
- 4. Tailored rehabilitation including a combination of psychological and physiological counselling with work place modifications

The program is delivered by a case manager, a RTW-team consisting of rehabilitation professionals from physical therapy and psychology and a clinical unit consisting of a psychiatrist and one of the following medical specialties; occupational health, social medicine or general practice. The program is tailored specifically to meet the need of each participant. Both the control and the intervention group receive a baseline questionnaire at inclusion, a six months follow-up questionnaire and are followed-up in a national register of social transfers including sickness benefits.

Previous interventions:

The municipalities were assigned to the control and intervention group using a stratified allocation procedure. The initial selection of municipalities was based on applications from 43 municipalities. All applications were assessed for quality and feasibility of implementation plans resulting in a total of 33 municipalities. These municipalities were grouped in distinct strata based on their size, socio-economic profile and organisation of the RTW-programme. Finally a stratified cluster selection was performed resulting in 11 municipalities (representing 14 offices) in the intervention group and 8 municipalities (representing 12 offices) in the control group. All control municipalities were offered the intervention after the end of the study.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

- 1. Duration of sickness absence
- 2. Time until RTW (becoming self-supporting)
- 3. Time until reoccurrence of long-term sickness absence (greater than 3 weeks) Measured from inclusion into the study until end of follow-up

Secondary outcome measures

- 1. Changes in self-rated health, mental and physical health and mental disorders (SF-12, SCL8-AD) six and twelve months after inclusion in the study
- 2. Changes in workability (single item), pain ('pain intensity', single 10 point Visual Analogue Scale (VAS) scale and 'pain beliefs' 3 items modified from Tampera Scale of kinesiophobia), and sleep patterns (Karolinska Sleep Questionnaire) six and twelve months after inclusion in the study
- 3. Municipal sickness benefit expenses, the level of production (earnings) and municipal and central government transfer payment expenses

(Please note, twelve month measure in points 1 and 2 added 14/11/2011. Previously only six)

Overall study start date

01/04/2010

Completion date

31/03/2012

Eligibility

Key inclusion criteria

Citizens on long-term sickness absence (greater than 4 weeks) registered as a 'category 2 case' (citizens in category 2 are according to Danish legislation guidelines assumed to be unable to return to work within a three months period, but to be able to gradually return to work). Citizens of either sex and any age can be included.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Intervention: approx 12,600: Control: approx 6,900

Key exclusion criteria

- 1. Citizens on sickness absence related to pregnancy
- 2. Citizens on sickness absence longer than four months at inclusion

Date of first enrolment

01/04/2010

Date of final enrolment

31/03/2012

Locations

Countries of recruitment

Denmark

Study participating centre Lersø Parkallé 105

Copenhagen

Denmark 2100

Sponsor information

Organisation

Danish Prevention Fund (Forebyggelsesfonden) (Denmark)

Sponsor details

Landskronagade 33 Copenhagen Denmark 2100 +45 (0)7220 9260 kontakt@forebyggelsesfonden.dk

Sponsor type

Research organisation

Website

http://forebyggelsesfonden.dk

Funder(s)

Funder type

Funder Name

Danish Prevention Fund (Forebyggelsesfonden) (Denmark)

Funder Name

Beskæftigelsesministeriet

Alternative Name(s)

Ministry of Employment, Danish Ministry of Employment

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Denmark

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/03/2012		Yes	No
Results article	results	01/04/2016		Yes	No