The Danish National Return To Work program (Det store TTA-projekt): a study in three 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 04/02/2011	Recruitment status No longer recruiting	 Prospectively registered [X] Protocol
Registration date 31/03/2011	Overall study status Completed	 Statistical analysis plan [X] Results
Last Edited 03/02/2023	Condition category Other	Individual participant data

Plain English summary of protocol

Background and study aims

Being on long-term sickness absence involves not only a health risk. People on long-term sickness absence also have an increased risk of losing their jobs and being excluded from the labour market. Many sick-listed persons need help to get out of the difficult situation, so that they can continue to enjoy a meaningful life at work. The Danish National return to work (RTW) program builds on the experience of a number of smaller RTW trials (Danish and foreign). The program includes three approaches that have been shown to have a positive effect on RTW for people on sickness absence: an interdisciplinary assessment of barriers and resources for returning to work, increased coordination between worker, workplace, healthcare and social insurance systems, and early initiation of RTW activities (counselling, education, on-the-job training etc.). The aim of this study is to evaluate the effects of the Danish RTW program have a shorter duration of sickness absence and a faster and more sustainable RTW. We will also test whether the RTW program is cost-effective.

Who can participate?

The participants are working-age adults on long-term sickness absence (at least four weeks) recruited from sickness benefit offices in three Danish municipalities (Copenhagen, Silkeborg and Esbjerg). According to the Danish Sickness Benefit Legislation, all sick-listed persons are categorised into three categories by the municipal sickness benefit offices. The present study includes persons in category 2 (persons who are not likely to fully return to work within three months, but currently able to participate in RTW activities or gradually return to work).

What does the study involve?

The three municipalities all have multiple sickness benefit offices, of which some are assigned the intervention while the others proceed with normal sickness absence management. The sickness benefit offices assigned the intervention will establish RTW teams comprising an RTW coordinator (typically an experienced social worker who will receive extensive training), a psychologist and a physiotherapist/occupational therapist; they will also establish a close link to a clinical team comprising a psychiatrist and a medical doctor. The RTW coordinator becomes the focal point for coordination between the relevant stakeholders, including employers, healthcare services, unions and unemployment funds and the RTW team and the clinical team. Data for the evaluation will be obtained from questionnaires, municipal data and national register data.

What are the possible benefits and risks of participating?

Participants will be assigned an RTW coordinator who will be their contact-person throughout the sickness absence period. They will experience a faster and more interdisciplinary assessment process and will receive increased coordination and earlier initiation of RTW activities compared with ordinary sickness benefit management. We expect that these improvements will shorten the average duration of sickness absence and promote a faster and more sustainable RTW.

Where is the study run from?

This study takes place in three municipalities in different parts of Denmark (Copenhagen, Silkeborg and Esbjerg). The main coordination and evaluation will take place at the National Research Centre for the Working Environment in 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 Lersø Parkallé 105 2100 Copenhagen Denmark

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

Contact information

Type(s) Scientific

Contact name Dr Otto Melchior Poulsen

Contact details Lersø Parkallé 105 Copenhagen Denmark 2100

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

The Danish National Return To Work (RTW) program: a randomised controlled study of a coordinated and multidisciplinary RTW program in three municipalities aiming to reduce the duration of sickness absence and to enable earlier return to work for persons on long-term sick leave

Study objectives

The overall objective of the intervention is to promote return to work 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

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

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s) Other

Study type(s) Treatment

rreatment

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

The intervention is conducted within the municipalities of Copenhagen, Silkeborg and Esbjerg. These municipalities are selected because they all have geographically separated sickness benefit offices allowing randomisation within the municipality. Randomisation is conducted by social insurance officers using a web-administrated program ('Inquisite') randomly assigning eligible citizens to either a sickness benefit office providing the RTW programme or standard case management. Participants receiving standard case management are designated as controls whereas participants receiving the RTW programme are designated as intervention participants.

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 workplace 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 6-month follow-up questionnaire and are followed-up in a national register of social transfers including sickness benefits.

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) 6 and 12 months after inclusion in the study

 Changes in workability (single item), pain ('pain intensity', single 10-point Visual Analogue Scale [VAS] scale and 'pain beliefs' - three items modified from Tampera Scale of kinesiophobia), and sleep patterns (Karolinska Sleep Questionnaire) 6 and 12 months after inclusion in the study
 Municipal sickness benefit expenses, the level of production (earnings) and municipal and central government transfer payment expenses

(Please note, 12-month measure in points 1 and 2 added 14/11/2011. Previously only 6 months)

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 3-month 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 Other

Sex Both

Target number of participants Intervention: ~ 3,500; Control: ~ 3,000

Key exclusion criteria

- 1. Citizens on sickness absence related to pregnancy
- 2. Citizens on sickness absence longer than 4 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://www.forebyggelsesfonden.dk/in-english.html

Funder(s)

Funder type Government

Funder Name Danish Prevention Fund (Forebyggelsesfonden) (Denmark)

Funder Name

Ministry of Employment (Beskæftigelsesministeriet) (Denmark)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol article</u>	protocol	01/03/2012		Yes	No
Results article	results	01/01/2014		Yes	No
Results article	results	01/02/2015		Yes	No
Results article	results	01/04/2016		Yes	No
Results article		02/02/2023	03/02/2023	Yes	No