ISRCTN12846389 https://doi.org/10.1186/ISRCTN12846389

What knowledge and initiatives are applied by Danish employers when supporting employees with persistent post-concussion symptoms in returning to work and maintaining attachment to labour market?

Submission date
30/03/2022

Recruitment status
No longer recruiting

Registration date
03/05/2022

Overall study status
Completed

Last Edited
16/08/2023

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol
Background and study aims
Concussion is one of the most frequently used neurological diagnoses in the Danish healthcare system and constitute more than 90 % of all head traumas. It is estimated that approximately 25,000 patients yearly become diagnosed with concussion in Denmark but this is likely underestimated since some patients do not seek medical assistance after concussion.
Most patients experience spontaneous recovery within the first 2-3 weeks , but up to 40 % develop persistent post-concussion symptoms (PPCS) such as headache, dizziness, vision problems, sleep problems, fatigue, concentration and memory difficulties, emotional problems etc. lasting beyond the natural recovery period. While some recover during the first months, approximately 35 % will continue to have symptoms 3 to 6 months or more after the trauma, including post traumatic psychological reactions such as anxiety, stress and depression. The PPCS have a long lasting effect on labor market attachment and employees with PPCS may therefore need support to stay employed. A Danish study shows that 43 % of employees with PPCS loose their connection to the labour market 5 years after the trauma and that 19 % receive welfare payments indicating reduced working capability. Furthermore, 5 % end up leaving labor marked altogether by receiving health-related early retirement pension.
The aim of this study is therefore to gather knowledge on which work-associated initiatives are presently used by Danish employers in order to support return to work of employees with PPCS. Secondly, we aim to map the needs of the employers regarding their knowledge about PPCS in order to provide support for successful work reintegration and work maintanances in employees PPCS.
The results from the survey will inform the content of an information folder targeting employers regarding how to create the best circumstances for employees with PPCS during the return-to-work process.

Who can participate?
Employees aged 18 - 65 years with PPCS lasting more than 4 weeks, who have experienced return to work within the last 12 months. It is furthermore required that the participants have been gainfully employed under regular conditions at the moment of head trauma.

What does the study involve?
The study is a national survey design where the participants and their employer complete the survey from home. The participants complete one survey (at the start of the study), and the employer completes two surveys: one about the return of the employee to the workplace some months after the employee has been enrolled in the study (1st follow-up) and one about maintaining the affiliation with the workplace 4 to 5 months after first follow-up (2nd follow-up).

What are the possible benefits and risks of participating?
The participants will not experience a direct benefit from participating, but they will contribute to the improvement of conditions of future PPCS employees. There are no direct risks associated with study participation.

Where is the study run from?
University of Copenhagen (Denmark)

When is the study starting and how long is it expected to run for?
August 2021 to February 2023

Who is funding the study?
Velliv Foreningen (Denmark)

Who is the main contact?
Hana Mala Rytter, hana.mala@psy.ku.dk

Contact information

Type(s)
Principal Investigator

Contact name
Miss Hana Rytter

ORCID ID
http://orcid.org/0000-0002-2910-372X

Contact details
Center for Hjernerystelse
Amagerfælledvej 56A
Copenhagen
Denmark
2300
+45 21651533
hana.mala@psy.ku.dk

Type(s)
Public

Contact name
Miss Irene Conradsen

Contact details
Amagerfælledvej 56 A
København S
Denmark
2300
+45 51430312
irene.conradsen@cfh.ku.dk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
514-202-21-2000

Study information

Scientific Title
Return to work after concussion - A survey of employees with persistent post-concussion symptoms and their employers regarding the initiatives to support reintegration in the work environment

Acronym
ARCOMS

Study objectives
1. Employers feel they lack sufficient knowledge about persistent symptoms after concussion and are unsure about the initiatives that can support their employees with lasting post-concussion symptoms in returning to work.
2. The survey will show that in most cases only a few of the possible work related initiatives were applied
3. Smaller companies will offer less initiatives to their employees with persistent post-concussion symptoms compared with larger companies
4. Employees with higher education will be offered more work related initiatives to return to work after concussion
5. There is a moderate correlation between higher amount of work relates initiatives and attachment to the labor marked

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/08/2021, The Institutional Ethical Review Board, University of Copenhagen, Department of Psychology (ØSTER FARIMAGSGADE 2A, 1353 KØBENHAVN K, Copenhagen, Denmark; +45 35 32 49 25; jan.nielsen@psy.ku.dk), ref: IP-IRB/17082021

Study design
Cross-sectional multicenter observational survey study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Home

Study type(s)
Quality of life

Participant information sheet
The participant information sheet (only in Danish) is available upon request to the study contact persons.

Health condition(s) or problem(s) studied
Concussion or minor traumatic brain injury

Interventions
This will be a survey study of employees with persistent post-concussion symptoms and their employers. One survey will be conducted on the employees (at the start of the study) and two surveys will be conducted on their employers at approximately 5 months and 10 months after their employees were enrolled in the study.

The employee survey at baseline will collect information about symptom severity via The Rivermead Post-Concussion Symptom Questionnaire (RPQ), and data on work-related activities via the Work Productivity and Activity Impairment Questionnaire (WPAIQ)) and The Work Role Functioning Questionnaire v2.0 (WRFQ). The employee surveys will be used to inform the development of the employer surveys.

The first of the employer surveys will be about the return of the employee to the workplace ~5 months after the employee has been enrolled in the study (1st follow-up) and the second about maintaining the affiliation with the workplace 4 to 5 months after first follow-up (2nd follow-up). These surveys consist of several validated questionnaires and specific survey questions developed by the scientists and clinicians participating in the study.

Intervention Type
Other

Primary outcome measure

Work-related initiatives (i.e. amount and type) that are applied across a variety of work places (i.e. public vs. private, small vs. large companies) in Denmark measured using employer surveys at 5 and 10 months

Secondary outcome measures
Knowledge regarding the needs of the employers in order to support successful reintegration in the work place for employees with persistent post-concussion symptoms with the aim of ensuring long-term labor marked attachment measured using employer surveys at 5 and 10 months

Overall study start date
17/08/2021

Completion date
01/02/2023

Eligibility

Key inclusion criteria
Employees:
1. Between 18 and 65 years old
2. Suffering from persistent post-concussion symptoms diagnosed by a physician
3. Danish speaking
4. Being employed under regular terms prior to concussion or fully available and job seeking prior to concussion
5. Having experience with returning to work after their concussion within the last 12 months

Employers:
6. Danish or English speaking

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100 persons with persistent post-concussion symptoms

Total final enrolment
92

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment
01/10/2021

Date of final enrolment
06/09/2022

Locations

Countries of recruitment
Denmark

Study participating centre
The Danish Concussion Center
Amagerfælledvej 56A
Copenhagen
Denmark
2300

Study participating centre
Center for Hjerneskade
Amagerfælledvej 56A
Copenhagen
Denmark
2300

Study participating centre
Kommunikationscentret Region Hovedstaden
Rygårds Alle 45
Hellerup
Denmark
2900

Study participating centre
CSV Kolding
Skovvejen 1B
Kolding
Denmark
6000

Study participating centre
CSV Vejle
Solsikkevej 6
Vejle
Denmark
7100

Study participating centre
VISP Næstved
Birkebjerg Allé 3
Næstved
Denmark
4700

Study participating centre
CfK Herning
Brahmsvej 8
Herning
Denmark
7400

Study participating centre
CSU Slagelse
Rosenkildevej 88 B
Slagelse
Denmark
4200

Study participating centre
Cervello AS
Høstvej 3
Kongens Lyngby
Denmark
2800

Study participating centre
CKV Odense
Heden 11
Odense
Denmark
5000

Sponsor information

Organisation
University of Copenhagen

Sponsor details
Institut of Psychology
Øster Farimagsgade 2A
Copenhagen
Denmark
1353
+45 21651533
christina.molin@samf.ku.dk

Sponsor type
University/education

Website
https://psy.ku.dk/

ROR
https://ror.org/035b05819

Organisation
Danish Center for Concussion

Sponsor details
Amagerfælledvej 56A
Copenhagen
Denmark
2300
+45 51430312
irene.conradsen@cfh.ku.dk

Sponsor type
Research organisation

Website
www.dfch.dk

Funder(s)

Funder type

Charity

Funder Name
Vellivforeningen (Live well foundation)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-review journal

Intention to publish date
01/12/2024

Individual participant data (IPD) sharing plan
The data can be made available upon request to the main contact person (hana.mala@psy.ku.dk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			04/01/2023	No	No