ISRCTN17016944 https://doi.org/10.1186/ISRCTN17016944

How can you sleep well and enjoy your lifestyle when you are a night worker?

Submission date
04/06/2019

Recruitment status
No longer recruiting

Registration date
12/06/2019

Overall study status
Completed

Last Edited
05/04/2024

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
The majority of night workers have difficulty sleeping. Between 8 and 30% of them suffer from the shift work disorder associated with their work schedule (SWD). Significant negative consequences, both for the worker and for the society, result from this problem. It is associated with an increased risk of depression, morbidity and gastric ulcers as well as an increase in absenteeism and accidents at work. When they experience insomnia, night workers have psychological distress. Their sleep difficulties can be explained mainly because the work schedule causes night workers to sleep when their biological clock promotes awakening. However, it has been suggested that psychological factors, such as the presence of depressive symptoms, or social factors, such as job satisfaction, play a role in the evolution of these sleep difficulties. Our first study shows that night workers may suffer of SWD in any of their sleep periods and that very few receive help. This study identifies the importance of cognitive activation at bedtime and anxiety state in difficulties of sleep experienced. The current study aims to further conceptualize the SWD. The effectiveness of interventions for SWD will also be studied. The project studies the sleep, awakening and social-psychological state of the night worker with or without difficulty sleeping in various urban areas. The expected results will provide new knowledge as to the understanding of sleep difficulties in night workers and will offer a first approach behavioural intervention. Based on progress achieved so far, the focus of the current proposal is on pursuing the exploration of psychosocial determinants of SWD with 120 participants.

Phase 1 consist in a 3-hour evaluation meeting (2 interviews on sleep and mental health, plus a 30-minute questionnaire to fill) and two weeks of online sleep diary and actigraphy (which consist of wearing a watch measuring luminosity and movement) and a 30 minutes meeting two weeks later. Phase 2 consists in testing with 40 SWD participants an adapted version of Behavioral Therapy for Insomnia (BT-I). The treatment includes six 50-minutes individual meetings, which focuses on a combination of sleep restriction and stimulus control, adapted to SWD.
Once participants have been screened and completed questionnaires at Phase 1, they will be divided in two groups, that is those presenting SWD or not. In a randomized designed with waiting group (waiting condition is 4 weeks) SWD participants receive an adapted BT-I and Outcome evaluations will be conducted two weeks before treatment, two weeks after treatment and six months after the end of treatment.

participants will receive 50$CAN contribution for participating in Phase 1 and a written report on their sleep, so they can expect to acquire new knowledge about their sleep pattern. For participants taking part in treatment (Phase 2), it may result in improved sleep and reduced sleepiness. Participation in this research project will also advance knowledge about sleep difficulties experienced by night workers and their treatment. Based on the current state of knowledge, there is no risk associated with participation in this study. It is possible that some questions may create discomfort; participants are free to ask for clarification or not to answer the question. During the indicated periods of the experiment, some discomfort may occur when wearing the actigraph, such as sweating or light wrist weight. If necessary, it will then be possible to change the bracelet or wear the actigraph only during sleep periods. Finally, sleepiness may increase during the first few weeks of treatment. If this is the case, measures will be taken by the intervener to quickly adjust the treatment and minimize this inconvenience.

All the research activities will take place at our research laboratory at (CERVO Brain research center), or for participants living far away from the research center, by Skype. The main contact is Professor Annie Vallières

Background and study aims
The majority of night workers have difficulty sleeping. Between 8 and 30% of them suffer from shift work disorder associated with their work schedule (SWD). Significant negative consequences, both for the worker and for the society, result from this problem. It is associated with an increased risk of depression, morbidity and gastric ulcers, as well as an increase in absenteeism and accidents at work. When they experience insomnia, night workers have psychological distress. Their sleep difficulties can be explained mainly because the work schedule causes night workers to sleep when their biological clock promotes awakening. However, it has been suggested that psychological factors, such as the presence of depressive symptoms, or social factors, such as job satisfaction, play a role in the evolution of these sleep difficulties. Night workers may suffer from SWD in any of their sleep periods and very few receive help. This study identifies the importance of cognitive activation at bedtime and anxiety state in the sleep difficulties experienced. The current study aims to further conceptualize the SWD. The effectiveness of treatment for SWD will also be studied. The project studies the sleep, awakening and social-psychological state of night workers with or without difficulty sleeping in various urban areas.

Who can participate?
Adults over the age of 18 working in night shifts (i.e. 24:00 and 8:00, ± 1 hour) for at least five nights out of 14 days for at least three months in Quebec hospitals and their research centres, health and social services centres, long-term care residential centres, and residences for the elderly.

What does the study involve?
Phase 1 consists of a 3-hour evaluation meeting (two interviews on sleep and mental health, plus a 30-minute questionnaire to fill), two weeks of online sleep diary and actigraphy (which consists of wearing a watch measuring light and movement) and a 30-minute meeting two weeks later. After Phase 1, the research team identifies participants as having shift work disorder (SWD) or not. The research team then invites participants with SWD to take part in Phase 2. Participants with SWD are randomly allocated to the treatment or waiting group (4 weeks). The treatment, a Behavioral Therapy for Insomnia (BT-I) adapted to SWD, includes six 50-minute individual meetings over 8-10 weeks, which focus on a combination of sleep restriction and stimulus

control. Participants complete an online sleep diary and wear actigraphs during the treatment and during 2 weeks after the treatment. The research team assess participants 2 weeks before treatment, 2 weeks after treatment and 6 months after the end of treatment.

What are the possible benefits and risks of participating?
As benefits, in addition to the financial compensation of $50, participant will receive a written report on his or her sleep at the end of participation in Phase 1. The research coordinator will explain the report and the participant sleep portrait. The participant can therefore expect to acquire knowledge about his or her sleep. There are also possible benefits to participants taking part in treatment (Phase 2): improving sleep and reducing sleepiness. Participation in this study will also advance knowledge about sleep difficulties experienced by night shift workers and their treatment. Based on the current state of knowledge, there is no risk associated with participation in this study. Some questions may cause discomfort; participants are free to ask for clarification or not answer the question. During the indicated periods of the study, wearing the actigraph may cause some discomfort, such as sweating or light wrist weight. If necessary, it will be possible to change the bracelet or wear the actigraph only during sleep periods. Finally, sleepiness may increase during the first few weeks of treatment. If this is the case, the intervener will take steps to quickly adjust the treatment and minimize this inconvenience.

Where is the study run from?
All the research activities will take place at the research laboratory at CERVO Brain Research Center, or for participants living far away from the research center, by Skype.

When is the study starting and how long is it expected to run for?
October 2014 to May 2022 (updated 05/05/2020, previously: January 2022)

Who is funding the study?
Canadian Institutes of Health Research (Canada)

Who is the main contact?
Prof. Annie Vallières
Annie.Vallieres@psy.ulaval.ca

Contact information

Type(s)
Scientific

Contact name
Prof Annie Vallières

ORCID ID
https://orcid.org/0000-0002-9433-7880

Contact details
Pavillon Félix-Antoine-Savard, local 1044
Sciences sociales - École de psychologie
Université Laval
2325, rue des Bibliothèques
Québec
Canada

G1V 0A6
+1 (0)418 656 2131 poste 408258
annie.vallieres@psy.ulaval.ca

Additional identifiers

Protocol serial number
IRSC 110524

Study information

Scientific Title
Night shift and sleep difficulties: psychosocial determinants and psychological intervention

Acronym
Sleep in night shift

Study objectives
This study is recruiting people working on night shifts on a continuous or fragmented schedule and is conducted in two parallel phases. It combines two specific objectives. First, it aims to investigate the specificities between shift workers following a continuous schedule and those working on a fragmented schedule in terms of sleep variables and (b) psychological and social variables (sleep defenders). Second, the project aims to evaluate the effectiveness of a behavioural therapy for insomnia (BT-I) adapted for shift work disorder (SWD) that is defined as the presence of insomnia and/or excessive sleepiness occurring in temporal relation to work schedule (International Classification of Sleep Disorders-III (American Academy of Sleep Medicine, 2014).

The guiding assumptions for each objective are based on the preliminary results. Special attention will be paid to social variables by studying the territorial space in different urban environments. No directive hypothesis is formulated for the social section of urban comparisons because of its exploratory nature.

Phase 1:
Objective 1: Specificity of the continuous and fragmented schedule

Sleep Variables
1. Fragmented shift workers will have a longer total wake time for the main period and for 24 hours than continuous shift workers
2. Fragmented shift workers will have a shorter total sleep time for the main period and for 24 hours than continuous shift workers
3. Fragmented shift workers with SWD will experience a higher degree of sleepiness than other workers
4. SDW shift workers will have a shorter total sleep time for the main period and for 24 hours than good sleepers shift workers
5. SWD shift workers will have a longer total wake time for the main period and for 24 hours than good sleepers shift workers

Psychosocial Variables (Sleep Defenders)
1. Continuous shift workers will experience greater severity of psychological distress than

fragmented shift workers
2. SWD shift workers will have a higher level of dysfunctional sleep-related beliefs and intrusive sleep thoughts than good sleepers shift workers
3. SWD shift workers will stay longer in bed than good sleepers shift workers

Phase 2:
Objective 2: Compared to SWD shift workers waiting for treatment, those receiving treatment will report:
1. An improvement in their daytime and nighttime sleep as measured by increased sleep efficiency, total sleep time, and decreased wake-up time
2. An improvement in their psychological distress as measured by a decrease in the severity of depressive and anxious symptoms and an increase in their quality of life
3. A decrease in cognitive activation and intrusive thoughts while falling asleep
4. Greater satisfaction at work and in their daily occupations

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/11/2015, Ethics Committee for Sectorial Research in Neurosciences and Mental Health at the Québec's University Institute of Mental Health, University Integrated Center of Health and Social Services, Quebec City (CER-S en neurosciences et santé mentale, CIUSSS de la Capitale-Nationale, Institut universitaire en santé mentale de Québec, 2601, chemin de la Canardière, Bureau F-1865, Québec, G1J 2G3; Tel: +1 (0)418 821 9661 – de l'IUSMQ, ext: 7879; Email: claire.billet@crulrg.ulaval.ca), ref: #407-2015

Primary study design
Interventional

Study design
Phase 1: observational
Phase 2: interventional randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Shift work disorder

Interventions
Based on progress achieved so far, the current proposal focuses on further exploring the psychosocial determinants of shift work disorder (SWD) with 120 participants (Phase 1) and testing (Phase 2) with 40 participants an adapted version of BT-I to this population (20 participants in treatment group, 20 participants in waiting condition (4 weeks) before receiving CBT-I).

The protocol used for Phase 1 is passive, observational and multifactorial. No random distribution is possible for this part of the study since there is no experimental manipulation. The design includes two factors. The first factor is the work schedule, containing two levels, either continuous or fragmented. The second factor is sleep disorder and consists of two levels, either the presence of shift work disorder (SWD) or good sleepers. Thus, a factorial design is

developed generating the following four groups: (a) shift workers with a continuous schedule with SDW; (b) shift workers with continuous schedule good sleepers; (c) shift workers with a fragmented schedule with SWD; and (d) shift workers with fragmented schedule good sleepers.

Participants who express interest following the publicity of the study are contacted by telephone for a 15-minute telephone interview to determine eligibility. Thereafter, eligible persons are invited to the sleep laboratory for evaluation in Phase 1. Two individual diagnostic interviews are then conducted by two different investigators: one for sleep disorders' screening and one for psychopathologies screening. The participants also answer a series of online questionnaires on health, depression, anxiety and sleep. The researchers then take participants measurements (weight, height) and check blood pressure while lying and sitting. For two weeks, participants wear an actigraph and fill out an online sleep diary. At the end of these two weeks, a meeting is held with the research coordinator to resume participants sleep following the two weeks evaluation.

Participants who have been diagnosed with SWD will be invited to join Phase 2. For Phase 2, the protocol is an interventional randomized design with a waiting group (the randomization is done by picking a sealed envelope). Participants in the treatment group will receive a free adapted behavioral treatment for insomnia (BT-I). Participants in the waiting condition will have to answer the online questionnaires again, to wear the actigraph to and to fill out the online sleep diary for two weeks before receiving BT-I (post-waiting condition).

The combination of sleep restriction and stimulus control adapted to SWD administered in Phase 2 is described in the researchers' treatment manual published as a book chapter (Vallières & Bastille-Denis, 2012). The use of the manual ensures processing accuracy. Sleep restriction (Spielman & al., 1987) and stimulus control (Bootzin, 1972) are known for their effectiveness in insomnia alone (Vallières & Bastille-Denis, 2012; Morin, 2004), or comorbid with different problems (Morin & Espie, 2003; Savard & al., 2005). Among other things, they contribute to reduce cognitive activation at bedtime. These interventions are effective within five to eight weeks with or without a separated week between sessions (Savard & al., 2005; Edinger & al., 2000). The treatment includes six 50-minute individual meetings. The first four meetings are administered weekly as much as possible, taking into account the participant's schedule and the sleep windows to be consolidated (day or night), while the last two meetings are given every two weeks, always taking into account the participant's schedule and availability. The first meeting includes psychoeducation on sleep, circadian rhythm and SWD as well as the introduction of sleep restriction and stimulus control. Their application is maintained throughout the treatment. Sleep restriction applies first to night sleep, then to day sleep and then to naps.

Outcomes will be assessed 2 weeks before therapy, 2 weeks after therapy and in a 6-month follow-up. The protocol allows the evaluation of the treatment effect at different times (Kazdin, 2003). It allows a comparison between groups by comparing the post-treatment of the experimental group with the control group post-waiting condition and an intra-group comparison by comparing the first three evaluations of the waiting list group (pre, post-treatment, post-treatment). Two weeks after the treatment, the online questionnaires are filled again by the participants, the sleep disorders' screening interview is conducted one more time and data are collected with actigraph and online sleep diary. Six months after treatment, online questionnaires are filled again with two weeks of an online sleep diary.

Intervention Type
Behavioural

Primary outcome(s)

1. The following sleep variables are calculated for each sleep period (main, 24-hour, naps and night): total wakefulness time (total waking time from bedtime to bedtime), sleep latency, total sleep time (TST; bedtime to bedtime sleep time) and sleep efficiency (ratio of TST to total bedtime) with the actigraph (Respironic). The actigraph is worn like a watch and records the movement continuously using a microprocessor. Actigraph is worn for 2 weeks at baseline, in the waiting condition 2 weeks before receiving treatment, during the whole treatment (8 to 10 weeks), 2 weeks after treatment and 2 weeks, 6 months follow-up after the treatment.
2. The following sleep variables are calculated for each sleep period (main, 24-hour, naps and night): total wakefulness time (total waking time from bedtime to bedtime), sleep latency, total sleep time (TST; bedtime to bedtime sleep time) and sleep efficiency (ratio of TST to total bedtime) with an online sleep diary. The sleepiness questions contained in the sleep diary are taken from the Stanford Sleepiness Scale. When the participant wakes up, he or she answers online questions about his or her sleep. Sleep diary is completed during 2 weeks at baseline, in the waiting condition 2 weeks before receiving treatment, during the whole treatment (8 to 10 weeks length), 2 weeks after treatment and during 2 weeks, 6 months follow-up after treatment.
3. Sleep quality, latency, duration and effectiveness as well as diurnal consequences are measured with Pittsburgh Sleep Quality Index (IQSP). IQSP is completed online at baseline, in the waiting condition 2 weeks before receiving treatment, 2 weeks after treatment and 6 months follow-up after treatment.
4. The degree of sleepiness is assessed by the Epworth's Sleepiness Scale completed online at baseline, in the waiting condition 2 weeks before receiving treatment, 2 weeks after treatment and 6 months follow-up after treatment.
5. The severity of insomnia is assessed by Insomnia Severity Index - day/night is completed online at baseline, in the waiting condition 2 weeks before receiving treatment, 2 weeks after treatment and 6 months follow-up after treatment.

Key secondary outcome(s)

1. Participant's eligibility is assessed with a 15 minutes' telephone questionnaire at baseline.
2. Work schedule and the reasons for working at night are measured with a questionnaire called Your Work Schedule at baseline
3. Presence of current or past psychological disorders are assessed with the MINI (Mini International Neuropsychiatric Interview), a semi-structured interview conducted at baseline
4. Presence of sleep disorders, their history, sleep patterns, precipitating and maintenance factors, temporal relationship between the onset of night work and sleep difficulties, information on the schedule and number of working hours are assessed with an adaptation of the Structured Insomnia Interview, a semi-structured interview conducted at baseline and 2 weeks after treatment
5. Vital functions and physiological parameters are measured at baseline and after the treatment as follows: participants are weighed and measured to derive the Body Mass Index. Blood pressure and heart rate are recorded while sitting, standing and lying down with a Life Style digital device.
6. Physiological activation is measured with three different questionnaires at baseline, in the waiting condition 2 weeks before treatment, 2 weeks after treatment and 6 months after treatment:
6.1. The medical history questionnaire (completed at baseline only) targets medical conditions, current and past medication use, physical activity level, meal times, cigarette and alcohol consumption
6.2. The Chronotype questionnaire measures whether a person is the morning type (best vigilance in the morning) versus the evening type (best vigilance in the evening)
6.3. The Activation Predisposition Scale measures the intensity of somatic and cognitive

activation symptoms.
7. Cognitive activation is measured with three different questionnaires at baseline, in the waiting condition 2 weeks before treatment, 2 weeks after treatment and 6 months after treatment. The Dysfunctional beliefs and attitudes about sleep questionnaire assesses beliefs and attitudes related to sleep and insomnia (misattribution or amplification of the causes of insomnia, concerns about sleep, unrealistic expectations about sleep, false beliefs about the consequences of insomnia). The Cognitive scale of the Activation Predisposition Scale measures the intensity of cognitive activation symptoms. The Glasgow Content of Thoughts Inventory (GCTI) assessed the frequency of intrusive thoughts at sleep.
8. Stimulus control (information on sleep pattern) are measured with initial interview (at baseline and 2 weeks after treatment), and with sleep diary and actigraph during 2 weeks at baseline, in the waiting condition 2 weeks before receiving treatment, during the whole treatment (8 to 10 weeks), 2 weeks after treatment and 2 weeks, 6 months follow-up after the treatment.
9. Emotions variables are measured with three different questionnaires at baseline, in the waiting condition 2 weeks before treatment, 2 weeks after the treatment and 6 months after treatment:
9.1. The Beck-II Depression Inventory assesses the severity of depressive symptoms
9.2. The situational anxiety and anxiety trait inventory assesses the state of anxiety that refers to situational anxiety and the anxiety trait that considers anxiety as a personality trait
9.3. The Diagnostic Inventory for Depression (DID) questionnaire assesses the relationship between work schedule and depression symptoms, the severity of depressive symptoms, the psychosocial rupture following the depressive state and subjective quality of life
10. Sleep facilitators are measured with four different questionnaires at baseline, in the waiting condition 2 weeks before treatment, 2 weeks after treatment and 6 months after treatment:
10.1. The job satisfaction scale (completed at baseline only) from the Standard Shift-Work Index assesses the level of job satisfaction
10.2. The territorial space questionnaire (completed at baseline only) gets information on civic address, the name and address of the workplace and the type of housing
10.3. The dyadic adjustment scale measures the level of distress and satisfaction of the couple
10.4. The questionnaire for evaluating healthy lifestyles assesses eating habits, physical activity, alcohol and tobacco consumption, stress management and professional life

Completion date
01/05/2022

Eligibility

Key inclusion criteria
1. Over 18 years old
2. Working during night shift at least five nights out of 14 days for at least three months in Quebec hospitals and their research centres, health and social services centres, long-term care residential centres, and residences for the elderly
3. Night work between 24:00 and 8:00 (± 1 hour)

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Phase 1:
1. Presenting a possible sleep disorder other than shift work disorder (SWD)
2. Present symptoms of SDW without meeting all the diagnostic criteria for this disorder (e.g., taking sleeping pills on a regular basis for sleep without having symptoms of insomnia)
3. Presenting with major depression with suicidal ideation
4. Presenting with a psychotic disorder or any disorders resulting from substance abuse
5. Being unable to answer questions during interviews or being unable to respond to questionnaires
6. Being visually impaired

Phase 2:
Two exclusion criteria are added:
7. Having consumed hypnotics on a regular basis in the last month (> 3 times per week)
8. Consuming more than 10 cups of coffee (or other stimulants) per day

Date of first enrolment
26/01/2016

Date of final enrolment
26/01/2020

Locations

Countries of recruitment
Canada

Study participating centre
Centre intégré universitaire en santé mentale (CIUSMQ) (University Integrated Center of Health and Social Services, Quebec City)
2525 boulevard de la Canardière,
Pavillon Landry-Poulin, 3ième étage
Quebec
Canada
G1J 2G3

Study participating centre

CHU de Québec - Université Laval (Laval University Hospital Centre)
Hôpital Saint-François d'Assises - local D7-704
10, rue de L'Espinay
Québec
Canada
G1L 3L5

Sponsor information

Organisation
Bureau de gestion des projets de recherche / Convenance institutionnelle CIUSSS de la Capitale-Nationale

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research

Alternative Name(s)
Instituts de Recherche en Santé du Canada, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as the researchers did not receive ethical approval for making the data available online when they asked their ethics committee. Anonymous data are kept on a computer in the laboratory without Internet access.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		05/03/2024	05/04/2024	Yes	No
Protocol file	in French	16/03/2015	28/12/2022	No	No