Brief Intervention for Sleep Medication Misuse Among Elderly (BI-sleep)

Clinical trials reg: NCT06032715

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Analyses plan for screening data (collected prior to randomisation of patients for RCT)

(Outcome measures 12-13 in registered protocol)

Clinical trials registration of screening data analyses plan – BI sleep study

Research questions:

- RQ1) what is the prevalence of potentially inappropriate z-hypnotics and other central nervous system depressant medication use in screened General Practitioners population?
- RQ2) what is the prevalence of self-reported sleep difficulties in screened population?
- RQ3) what is the relationship between potentially inappropriate z-hypnotics and self-reported sleep difficulties
- RQ4) What is the proportion of variance in z-hypnotic use on the GP level?

Descriptive statistics:

Characteristics of participants:

- Patients' gender and age, GP's gender, number of GPs participated and patients per GP included.

Prevalence of

- 1) Potentially inappropriate z-hypnotics (defined as use three times or more per week for more than four weeks, OR all user), and central nervous system depressant medication use (defined as continuous use) in screened GP population
- 2) Patient self-reported sleep difficulties on screening questionnaire, variables includes:
- Sleep difficulties (yes/sometimes, and no)
- Trouble falling asleep (yes or no), trouble staying a sleep (yes or no)
- Sleep difficulties related to pain, death in family, staying up thinking (yes or no).

Post hoc/explorative analysis qualitative (mixed methods).

Text analysis of comments from participant on reasons for sleep difficulties

Main analyses: Logistic random effects regression

Model 1:

Outcome: z-hypnotic use (defined by use three times or more per week for more than four weeks OR any use four last weeks (yes/no).

Random effect: GP

Fixed effect: patient gender, age, sleep difficulties.

Model 2:

Outcome: z-hypnotic use (defined by use three times or more per week for more than four weeks OR any use four last weeks) (yes/no).

Random effect: GP

Fixed effect: patient gender, age, sleep difficulties types.

Model 3:

Outcome: z-hypnotic use (defined by use three times or more per week for more than four weeks OR any use four last weeks) (yes/no).

Random effect: GP

Fixed effect: patient gender, age, sleep difficulties reasons.

Model 4:

Outcome: z-hypnotic use (defined by use three times or more per week for more than four weeks OR any use four last weeks) (yes/no).

Random effect: GP

Fixed effect: intercept only.

Post hoc/explorative analysis quantitative: Gender to gender differences between GPs and patients using z-hypnotics, benzodiazepine and opioids.