

The Norwegian Addiction, Pain and Trauma study

(NOR-APT)

NCT-number: Not yet available

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1. Sample size calculations (written May 16th 2021)

The sample size needed to estimate prevalence of chronic pain in each subgroup of substance dependent patients is n=384 assuming a prevalence of 50% (previous studies have found the prevalence to be as high as 54% among opioid dependent patients in Norway) and n=323 assuming a prevalence of 30% (similar to that in the general population in Norway). As there are not many clear estimates of chronic pain among patients with other types of substance dependence, the exact sample size required is difficult to calculate. Considering that there may also be missing data or incomplete questionnaires, we will aim to have 300-400 participants included for each subgroup of substance dependence, if possible. This sample size should also give sufficient power for comparisons between groups (independent samples t-tests or chi-square tests) and regression analyses, where power calculations estimate the need for a sample size of for instance n=105 in each group for independent sample t-tests.

2. Research questions and data analyses (translated from the Norwegian protocol submitted to the regional ethics committee south-east on November 4th 2020)

All analyses will be 2-sided with a set level for significance at 5%, or 95% confidence intervals.

We are not testing clearly formulated hypothesis, but will explore differences between different patient groups, as described in the research question section. Mainly, we will compare participant groups according to our three main outcomes: substance use pattern, chronic pain and stressful life events/post-traumatic stress symptoms. This means comparisons of patients grouped according to their primary substance use problem/substance use pattern, whether they report chronic pain or not, and according to types of stressful life events and level of post-traumatic stress symptoms. We will also investigate differences between women and men.

Comparisons will be made using independent sample t-test, chi-square tests and ANOVA tests. When looking at predictors, we will use adjusted regression analyses and mediator analyses.

Additional explorative analyses will be considered, as this is an exploratory study.

The specific research questions are listed below.

I. Describe the prevalence and characteristics of pain for people in need of treatment for substance/medication use/dependence.

For subgroups with different primary substance for dependence/ different substance use patterns, we will explore:

1. What is the prevalence of chronic pain?
2. What is the duration of the pain?
3. What are the causes of the pain?
4. Where on the body is the pain located?
5. What is the intensity of the pain?
6. How many have sought medical help for the pain and what treatment have they received?
 - a. Are there characteristics of the pain, of the participants' mental health or demographics that are related to whether they have sought help or received treatment for pain?

II. Describe how the pain affects physical and emotional functioning, and subjective quality of life.

For subgroups with different primary substance for dependence/ different substance use patterns, we will explore:

7. To what extent does the pain affect

- a. General activity
- b. Walking ability
- c. Normal work (including housework)
- d. Sleep
- e. Mood
- f. Relationships with other people
- g. Enjoyment of life
- h. Subjective quality of life

8. Are there characteristics of the pain, of the participants' mental health or demographics that are related to the degree of influence the pain has on physical and affective functioning (see research question 7 above)?

III. Explore any connections between substance/medication use and pain, both what came first and any ways substance/medication use and pain affect each other.

For subgroups with different primary substance for dependence/ different substance use patterns, we will explore:

9. What is the timeline for development of co-occurring chronic pain and substance use dependence?

a. How many develop pain before and after they began their substance use?

10. For participants with opioid use, for how many were the first opioid use motivated by relieving pain?

11. Are there differences in characteristics of the pain, participants' mental health or demographics for participants where pain came first compared to participants where substance use came first?

12. How many report that substance use has contributed to the cause of the pain?

13. Which substances/medications do the participants report as relieving the pain and which aggravate the pain?

14. How many report that pain or worry about pain is an obstacle to recovery from substance dependence?

15. Is there a connection between substance/medication use (type, frequency of use in the last 4 weeks and intravenous use) and:

a. Experience of pain intensity?

b. Degree to which the pain influences physical and affective functioning?

16. For opioid dependent patients in OMT, how does the development of pain relate to enrolment in OMT and the type of OMT medication they receive?

a. To what extent has pain influenced the choice of medication in OMT?

IV. Explore the connection between chronic pain, potentially traumatizing life events and post-traumatic symptoms.

For subgroups with different primary substance for dependence/ different substance use patterns, we will explore:

18. How many have experienced stressful life events (potentially traumatic)?

a. What types of stressful life events?

b. How many different stressful life events?

c. For how many was at least one stressful life event also physically painful?

19. What proportion experienced stressful life events before the pain occurred and how many after the pain occurred?

20. Does the type of stressful life events, age when the most troublesome stressful event occurred or level of post-traumatic stress symptoms influence:

a. Perceived pain intensity?

b. Degree of influence the pain has on physical and affective functioning?

Other topics that can be explored based on the collected data:

21. Can the participants be categorized into typical trajectories for onset of substance use, pain and stressful life-events?

a. Are there characteristics of pain, substance/medication use, stressful life events or demographic factors that characterize the different trajectories?