## Medi-TUNA prescribed medication-

# A longitudinal observational study of participants in a vocational rehabilitation program.

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#### Abstract

There is an increase in mental illness as well as an increase in sick leave in Sweden. A program called the TUNA-program has been a possibility for those with a background of unemployment or sick leave to get help to come back to working life through a vocational rehabilitation program over the course of one year. A medical evaluation of this program was performed to evaluate whether participation affects the health of the participants, with 100 patients included and followed up over a 24 months period. Previous economical evaluation had already shown this particular rehabilitation program to yield 9 SEK in return to each 1 SEK invested in the participants.

This study's focus was the 100 included participant's prescription medication for depression, anxiety, insomnia and pain; four symptoms/conditions that are common in mental health illness. The participants were included in a longitudinal study with data for a 24 month period. Data has been collected from questionnaires as well as from the patients' medical charts where their prescribed medications for treating depression, anxiety, insomnia and pain was recorded. The study's aim was to investigate whether there had been any changes in the participants' prescriptions of drugs in the above mentioned groups.

The participants included had a mean age of 37 years and 63% were women. Eighty-six percent were born in Sweden and 69% were living alone. The total number of prescriptions for depression, anxiety, pain and insomnia decreased during the study but the number of patients included is too small to draw any conclusions on whether there is a causality or not. The study showed no significant increase in prescription medication for the group and this was in concordance with previously published studies regarding their mental health status and overall health. The conclusion is that participation in the TUNA-project did not seem to deteriorate the participants' health also when looking at their number of prescriptions. The data of the study are to be treated with vigilance because of the small number of patients studied. There were also factors in the treating physician's possible lack of adherence when it comes to keeping the patient's record of medications up to date that influences the interpretation of data.

#### Background

The economic and social burden of sick leave and disability pension has for many years been a major subject of debate in Sweden. The number of persons on sick leave as well as the number on sick leave due to mental illness have been increasing in the last two decades (1). Globally there is an increase in mental illness and the costs, both for the individual and for society as well as the suffering, are vast(2). In Sweden the number of sick leave cases has, after a temporary drop in 2010 with 98200 longer sick leaves, increased again to 123000 cases in December 2014(1). The most recent data shows an increase to 142000 cases by December 2017(3) which is a 25,5% increase compared to 2010. This increase is greater than the population increase in Sweden which between 2010 to 2017 was 7,5%(4). The term "longer sick leave" is defined as absence from work due to illness for more than 60 days (5). Women account for 66% of the longer sick leave cases. Mental illness counts for 37% of sick leave for women and 27% for men. For women, mental health issues are the largest cause to sick leave. The number of persons on sick leave because of mental illness has had a steady increase since the late 1980-s in Sweden(1).

In 2008 a vocational training program "TUNA" was established in the City of Eskilstuna Sweden. "TUNA" is short for "Träning Utveckling Nära Arbetslivet" (training and development close to working life) (6). The program is a collaboration between Eskilstuna local council, the Swedish National Unemployment Agency (Arbetsförmedlingen), the Swedish Social Insurance Agency (Försäkringskassan) and participants from the healthcare sector, both primary healthcare and specialized psychiatric clinics in the county of Sörmland. The project was, after an evaluation of the economic gain by Sörmland Regional Council (RAR), made permanent in 2011 after the economic evaluation showed that each invested 1 SEK gave 9 SEK back in value over a five-year period (7). The individuals who participate in this program are often far from the labor market. The program has been described as a successful model to help individuals that are normally very far from employment make a first move towards regular work. However, the TUNA project has made about 1/3 of participants continue to paid work or studies after one year, which is a high number for this group (3).

Participants to TUNA are recruited from both primary healthcare and psychiatric care. To be eligible to enroll, the participants have to be on some form of sick leave; on social welfare,

unemployed or on sick leave but with any kind of disability that makes it impossible for them to return to their previous work place; and age 18 or above. The vocational rehabilitation is coordinated by special "coaches" that help the individuals find places for work training with a gradually increase in work hours during a period over a period of 12 months. The rehabilitation is managed by these coaches together with the participants and there is also cooperation and coordination with the other agencies involved.

There has been a research project that started in 2013 with 24 months follow up to evaluate if there were any health effects on the participants in the TUNA vocation training program called the "Medi-TUNA project". This project is sub-study of the Medi-TUNA project.

There are previously described interrelationships between mental illness, use of prescription medication, quality of life, longevity, and unemployment(8,9). There are also studies describing a link between drug prescription and longer periods of absence from work (10) as well as studies showing that individuals from lower socioeconomic status consume more psychotropic medication (11). However, it is also suggested in some research that low socioeconomic status (SES), which all of the TUNA participants have, is associated with a higher rate of discontinuation of medication for depression and that low SES is also associated with a higher incidence of prescriptions for depression, anxiety or insomnia (10,12), although other research claims this causality to be weak or non-existent (13). There are also a number of causes of poor adherence and discontinuation of prescribed medications such as presence of depression, inadequate follow-up, side effects of medication, patient's beliefs regarding the benefit of the treatment and also the cost of medication (14,15).

The aim of this project was to investigate whether there are any differences in prescription medication for treatment of depression, anxiety, insomnia and pain in a group of 100 participants TUNA project vocational rehabilitation at inclusion, during and after participation in vocational rehabilitation. The hypothesis was that previously published results regarding the participants' improved health should be corresponding to a decrease in prescriptions. The discrepancy between patient-reported medications compared to actual prescriptions was also described.

#### Methods

Within the project "Medi-TUNA", 100 consecutive participants were recruited for this study between August 2013 and September 2014. The participants were followed with a questionnaire in Swedish at inclusions and then at 6, 12 and 24 months respectively. The questionnaires were the same for all four follow-ups and consisted of questions regarding sociodemographic data, mental health and quality of life plus questions regarding the participant's view on their own health, questions regarding medication for depression, anxiety, sleep and/or pain and questions about smoking and alcohol intake. The Short Form 12-item survey (SF-12) was used for quality of life (16,17), the Hospital Anxiety and Depression Scale (HAD-S) (18) and the Montgomery-Åsberg Depression Rating Scale (MADRS-S) (19) was used for depression and anxiety. Alcohol habits were examined using the AUDIT-C (20). There were also questions regarding sleep, diet and exercise habits.

The answers for four questions regarding prescriptions to treat depression, insomnia, anxiety and pain were chosen for analysis. The mental health status for the participants has been described elsewhere (21).

Alongside questionnaire data, this study contained data from the patient's medical records. More specifically, data has been collected from the so-called "medication module" in the participant's digital chart, where all prescribed medications from all clinics in the county are registered. In Sörmland County Council all primary healthcare providers as well as the psychiatric clinics use the same digital platform and it is therefore possible to obtain data from all prescribing physicians. Both private and publicly owned health care providers are connected to this digital platform. The software used is NCS Cross, provided by Evry One AB (22). No data has been collected from the patients' medical chart where information about clinical status etc. is registered. Data has been collected for the dates corresponding to inclusion date as well as dates 6, 12 and 24 months after inclusion.

Prescribed medications were classified in four categories; drugs used for "depression", "anxiety", "insomnia" and "pain" respectively and the classification was done using both ATC numbers and indication as stated in FASS (pharmaceutical specialties of Sweden)(23) (appendix 2). All drugs that fell into the four above mentioned categories that were taken

into the questionnaire were registered at each measuring point. Therefore, all antidepressants were put in the same category which means that both newer drugs such as agomelatine and reboxetine are in the same category as older antidepressants like clomipramine. In the same manner, all anxiolytics were grouped in their own category. Other psychotropic drugs like anti-psychotics or drugs used to treat ADHD or bipolar disorder are not included in the analysis. Drugs to treat other diseases, both chronic and acute, such as hypertension, diabetes or hypothyroidism has not been included as there were no data regarding these conditions in the questionnaire.

Data were analyzed using SPSS. Simple cross-tabulations were made to illustrate the proportion of medication and also to correlate with what the patient's had claimed to take when answering the questionnaire. Independent sample T-test was performed for hypothesis test.

#### **Ethical considerations**

The participants were given written information and a signed consent was obtained. The study has been approved by the Regional Ethical Review Board of Uppsala, Sweden (D-no 2013/228). The study is based on questionnaire data as well as data collected from the patients' medical records which has been treated with the highest degree of integrity to protect the patients' right to privacy. Since the study is based on questionnaires and data collected from charts, the physical harm to the patients is non-existent. The psychological harm has been protected by keeping all data anonymized and has been stored in a way that ensures no access to persons outside the research group.

#### Results

One hundred patients were included in the study. However, 12 participants never finished their mapping process and/or didn't start their participation in the vocational training. These participants were still included in the analysis since their data of drug prescription could be obtained.

Of the 100 individuals at base-line 37 were men and 63 were women. Their mean age was 37 years (range 23-63).

Twenty-four (24%) had their highest level of education in lower secondary school. Fifty eight percent (N=58) had some form of upper secondary education and 10% (N=10) had any level of college or university education. Thirty percent (N=30) were married or in a domestic partnership while 69% (N=69) were single, one respondent did not answer this question. The majority (86%, N=86) were born in Sweden and 13% (N=13) in another country, one respondent did not answer this questionnaire 1, at inclusion. At 6 months 82 responded, at 12 months 56 responded and at the 24 month follow-up 41 responded.

Twenty-four participants had no prescription medication for depression, anxiety, insomnia or pain at baseline and that number had increased to 42 at the 24 month follow up. There was a significant decrease in prescription medication for the respondents to all 4 questionnaires when comparing baseline to the 12 month follow-up (P= 0.046), while there was no significant decrease in prescriptions of the "drop outs" when comparing the same points in time (P=0.110). However, the group of "drop outs" had a significant decrease when comparing baseline to the 24 month follow-up (P=0.035). This significance could not be observed in the group of respondents to the 24 months questionnaire (P=0.127).

There were 77 prescriptions for antidepressants at baseline, but as one patient can have more than one prescription for treating depression; this does not mean that there were 77 participants with an antidepressant. The number of prescriptions for depression decreased from 77 at baseline to 50 at 24 months when looking at all 100 patients. For the 41 patients who participated in the 24 month follow up, 21 prescriptions for treating depressions were found. (Table 1)

Further, there were 46 prescriptions for anxiety that had decreased to 38 at 24 months. For treating insomnia, 36 prescriptions were found at baseline and at 24 months 16 prescriptions were found. Another 18 prescriptions for pain were found at baseline but there was no real decrease at 24 months where there were 16 prescriptions and at the 12 month follow up there was even an increase to 27 prescriptions for treating pain. (Table 1)

			Time of follow up			
Drug type			Baseline	6 months	12 months	24 months
Antidepressants	Responded to questionnaire at follow up	Yes	77	57	31	21
		No	0	10	29	29
	Total		77	67	60	50
Anxiolytics	Responded to questionnaire at follow up	Yes	46	30	22	13
		No	0	11	20	25
	Total		46	41	42	38
Insomina	Responded to questionnaire at follow up	Yes	36	25	19	10
		No	0	5	7	6
	Total		36	30	26	16
Analgesics	Responded to questionnaire at follow up	Yes	18	13	13	9
		No	0	6	14	7
	Total		18	19	27	16
No prescription	Responded to questionnaire at follow up	Yes	24	23	19	17
		No	0	4	14	25
	Total		24	27	33	42
Total	Responded to questionnaire at follow up	Yes	214	160	113	73
		No	0	37	87	102
	Total		214	197	200	175

Table 1. All prescriptions for the four categories subdivided to respondents or nonrespondents at all four times of follow up.

Of the anxiolytics prescribed, only about 15% were classified as benzodiapzepines (diazepam or oxazepam) and of the pain medication about 10% were opioids (oxycontin or codeine) (Table 2).

			Drugs	
Drug type			No	Yes
Anxiolytics T f	Time of follow up	Baseline	37	9
		6 months	35	6
		12 months	35	7
		24 months	33	5
	Total		140	27
Insomnia Time of follow up	Time of follow up	Baseline	20	16
		6 months	13	17
		12 months	10	16
	24 months	24 months	5	11
	Total		48	60
Analgesics Tir fol	Time of follow up	Baseline	17	1
		6 months	17	2
		12 months	22	5
		24 months	14	2
	Total		70	10

Table 2: Amount of narcotics compared to all prescriptions for anxiolytics, drugs to treat insomnia and analgesics.

There was a discrepancy between the prescriptions found in the participant's charts and their answers in the questionnaire, where some have claimed to not have any medications for depression, anxiety, insomnia or pain but where there were active prescriptions from their treating physician at the time the observation was made (Table 3).

			Respo question: on a pharma treatm depres	nse to "Are you any ceutical ent for ssion?"
Time of follow up			Yes	No
Baseline	Prescription for	No	17	22
	antidepressants found	Yes	46	14
6	Prescription for	No	12	24
months	antidepressants found	Yes	37	9
12	Prescription for	No	6	23
months antidepressants found	Yes	23	4	
24	Prescription for	No	4	21
months	antidepressants found	Yes	15	3

Table 3: Crosstabulation to present the discrepancy between actual prescriptions found and

patient's reported drug intake of antidepressant.

		Response to questionnaire: "Are you currently using any medication to treat anxiety?"		
Time of follow up		Yes	No	
Baseline	Prescription for anxiolytics found	No	24	43
		Yes	12	20
	Total		36	63
6 months Pres anxi	Prescription for	No	17	39
	anxiolytics found	Yes	7	18
	Total		24	57
12 I months a	Prescription for anxiolytics found	No	18	21
		Yes	7	10
	Total		25	31
24 F months a	Prescription for anxiolytics found	No	13	19
		Yes	5	6
	Total		18	25
Total	Prescription for anxiolytics found	No	72	122
		Yes	31	54
	Total		103	176

Table 4: Crosstabulation to present the discrepancy between actual prescriptions found and patient's reported intake of anxiolytics.

#### Discussion

In this study of 100 patients, it has been observed that for the group who has participated in TUNA rehabilitation and responded to the questionnaire at all four follow-up, there has been a decrease in prescriptions. This might be due to a better health when being introduced to labour, as this could theoretically empower the participants and in extension give them an improved mental health. This theory was supported by previous research. (24)

The discrepancy between actual prescriptions found and the patient's stated drug intake is well in line with previous research, where numbers of up to 50 % lack of compliance has been observed in several studies (14,15,25,26). Also, there was unfortunately a high risk of the prescriptions record being wrong and the validity of the results is questionable. For various reasons, the treating physician did not always remove a prescription from the patient's chart after a decision has been made to end a treatment. This makes the data somewhat unreliable as there was a risk of "false positives", i.e. that there seems to be more prescriptions than what there should be. On a positive note, there was a low risk of "false negatives", i.e. that the patient was taking a medication despite the lack of prescriptions although it must be considered that some drugs can be obtained through the so-called "black market". Another possibility was that the patients who have stated to take drugs for depression might have bought herbal remedies without prescription which would then not be visible in the medications chart.

The number of patients with narcotics to treat anxiety or insomnia was 15% which shows that these patients are probably not over consuming prescribed narcotics and also that their physicians apply the recommendations by the regional pharmaceutical committee of Sörmland (Sörmlands läkemedelskommitté) (27) where non-narcotic anxiolytic agents are recommended primarily.

With regards to the methodology of this study, there are flaws. It would have been desirable to compare the prescriptions found in the patient's chart to data from the national pharmacies database to see what had actually been claimed by the patients. It would also have helped the interpretation of these numbers to look at the treating physician's medical chart of each patient and see their assessments of the patient's current status at the time of each follow-up. The lack of adherence by the physician to "clean up" the medical chart also affected how the data could be interpreted.

The data collected are of a small number and should therefore be treated with vigilance when it comes to causalities. However, there was not a significant increase in consumption of medication which indicates that participation in TUNA vocational rehabilitation does not worsen the participants' pre-existing conditions. This was in concordance with another evaluation made in the Medi-TUNA project where no decline in the participants mental health could be seen (21). When hypothesis tests were performed P-values suggested a significant decrease in prescription medications in both groups (both those who followed through all four questionnaires as well as those who did not reply to all four questionnaires). Though it could be interpreted as a sign of improved health in the participants these numbers must be seen as indications rather than strong evidence since the number of cases analyzed was so small.

This study, besides the information about the participant's prescriptions, also gives an important lesson to the treating physicians: it is vital that the patient's chart is accurate and that all treating physicians makes an effort to ensure that the changes in medication that has been made in agreement with the patient are also made in the patient's chart. Besides from facilitating the work of researchers, it is also important for the safety of the patient's health.

To conclude: it does not appear that participation in the TUNA vocational rehabilitation program leads to an increase in prescription medication, which corresponds to the previous evaluation of the participants' mental health where an improvement could be seen (21) if making the assumption that an increase in prescriptions would correlate to a decrease in mental helath. However, the data of this study are of a small number and with a high degree of uncertainty when it comes to interpretation due to many factors that could give false results.

#### Potential conflicts of interest:

None

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## Appendix 1

Medituna questionnaire:



## Appendix 2

Classification of prescribed drugs:

Depression	
SSRI/SNRI	ATC
Setralin	N06AB06
Citalopram	N06AB04
Mirtazapin	N06AX11
Fluoxetin	N06AB03
Venlafaxin	N06AX16
Escitalopram	N06AB10
Cymbalta - duloxetin	N06AX21
Paroxetin - Seroxat	N06AB05
Bupropion - voxra	N06AX12
Brintellix - vortioxetin	N06AX26
Edronax - reboxetin	N06AX18
Tricyclic	
Klomipramin	N06AA04
Tetracyclic	
Mianserin	N06AX03
MAO-inhibitor	
Saroten	N06AA09
Other antidepressants	
Valdoxan - agomelatin	N06AX22
Anxiety	
Bensodiazepines	
Oxascand - oxazepam	N05BA04
Stesolid	N05BA01

Other anxiolytics	
Atarax	N05BB01
Theralen	R06AD01
Lergigan Forte	R06AD02
Buspiron	N05BE01
Alimemazin	R06AD01
Lyrica	N03AX16
Insomnia	
Zopiklon	N05CF01
Propavan	N05CM06
Zolpidem	N05CF02
Circadin	N05CH01
Valerina Forte	N05CM09
Pain	
Tramadol	N02AX02
Paracetamol	N02BE01
Naproxen	M01AE02
Ibuprofen	M02AA13
Tradil	M01AE14
Diklofenak	M01AB05
Paraflex	M03BB03
OxyContin	N02AA05
Celebra - celecoxib	M01AH01
Citodon	N02AA59