Study protocol

At Work and Coping (AWaC)

Content

This study protocol has two parts: The technical protocol (Part A) presents the protocol as it was originally developed and presented before inclusion of the first participant. The dissemination protocol (Part B) has been updated during the project, includes key references, and has been expanded to provide a more detailed description of the trial, the intervention and control conditions, and modified to meet current standards and terminology in a rapidly developing field.

The technical protocol thus secures transparency and that presented results align with the original plan and pre-registered details. The dissemination protocol gives an up-to-date description of how the intervention and trial was planned carried out, to facilitate implementation and replication elsewhere.

A: Technical protocol

At Work and Coping (AWaC)

01.06.10

Title of the study:

A randomized controlled multicenter trial assessing the effect of the AWaC-program (At Work and Coping) for people with common mental disorders.

Funding source:

The trial is commissioned by the Norwegian Ministry of Health and Ministry of Labour, and financed through the National Strategy on Work and Mental Health (2007-2012).

Study numbers:

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Final protocol

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Background

Mental health problems, and in particular anxieties and depression, are increasingly recorded as the cause of sickness absence and diability pensioning. In 2007, the Norwegian Ministry of Labour and social inclusion ("Arbeids- og Inkluderingsdepartementet (AID))" and Ministry of Health and Care Services (Helse- og omsorgsdepartementet (HOD)) released a national strategy for work and mental health (2007-2012), where the need for novel research on work and mental health was addressed. In particular, the strategy pointed to a need for better evaluation of interventions aimed at helping people with common mental disorders increase their parcitipation in working life. One of the interventions that were funded through the naitional strategy was 3.1.c: At Work and Coping ("Jobbmestrende oppfølging"). After an open call for tender, Uni Health was asked to carry out an experimental evaluation of the intervention. In this protocol, we will describe how this study will be carried out.

About the AWaC program

The intervention to be evaluated, from now referred to as "At Work and Coping (AWaC)", targets people with common mental disorders (anxiety/depression) that either have a job and wish to keep working, or people without a current job but a desire to enter or re-enter working life. The intervention has built on experiences from a pilot project carried out in Østfold County in 2006-08 ("Østfoldmodellen"). The model is based on councelling delivered by clinical psychologists/councellors, where focus is directed towards coping of symptoms as well as guidance and support from an employment specialist who provides individual job support through assisting in adaptations at the work place, identifying an appropriate employer etc. The goal is to prevent people with common mental disorders from falling out of working life and help those with no current job back into employment.

The combination of short-term cognitive behavioural therapy and individual job support places the project on the demarcation between health care and occupational services. The Norwegian health care administration is not mandated to

run medical and psychological interventions. Even though the intervention employs methods developed for use in psychological therapies, the methods must be adapted for use in a non-health care setting. This influences the terminology used to describe the intervention. The combination of elements from health care and occupational services are thought to serve the complex and individual needs of the individual service user. The intervention is established and running at 6 centers. Service users are recruited both through NAV and directly from primary health care and occupational health services, in addition to self-referrals. Each of the centres employs three to four therapists (clinical psychologists), all with particular training related to the intervention.

Primary aim of the study

A coordinated and integrated intervention program has been lacking for people who struggle with work participation due to common mental disorders, and the AWaC program was developed to address this shortcoming. The primary aim of the study is to investigate if the AWaC program leads to increased work participation for people with common mental disorders compared to treatment as usual.

Secondary aims

The secondary aims of the study include the following:

1) Evaluate the effect of the AWaC program on mental health and quality of life. The evaluation will include a cost-benefit evaluation based on the effects demonstrated on work participation in the trial period. The effect evaluation will be conducted as a randomized controlled trial.

2) Evaluate potential sub-group effects of the AWaC program, to further contribute to the understanding of effective mechansims in the rehabilitation of people with common mental disorders. The target group of the study will be heterogeneous both in terms of work status and duration of mental health complaints, so a secondary aim will be to assess whether these characterstics influence the effect of the program.

3) Conduct a systematic analysis of how the AWaC program collaborates with the social insurance system in general and the primary health care system. The aim of this analysis will be to identify organizational challenges and solutions to obtain a more integrated and coordinated service for the individual user of the AWaC program. This part of the study will be conducted as a qualitative study involving interviews with responsible stakeholders (team leaders and therapists at the centres, collaborating institutions and user representatives).

About randomized controlled trials

The effect evaluation of the intervention (AWaC program) offered at the centres will be carried out as a randomized controlled multicentre study. Employing an experimental design (RCT) will in most cases mean that the effect evaluation is done though a comparison of effect between one or more intervention groups and one or more control groups. The intervention groups receive the intervention one wants to study the effect of, while the control groups receive an intervention where the effect is established or an intervention that is commonplace for the target group. After the respective interventions are administred and carried out, one can compare the effect for the intervention group with that of the standard in the control group. For any difference in effect to be ascribed to the intervention with certainty, there must be no systematic differences between the groups beyond the difference in interventions they have received. For example, there must not be any systematic difference in motivation, level of problems or prognosis between the groups. Any form of group allocation based on voluntary placement or judgement will increase the risk for such systematic differences to be introduced. To avoid this risk, one uses randomization, or random allocation, which means that it is completely random which group each individual participant ends up in. With an adequate number of participants, one can assume that differences, both known (observed) and unknown (unobserved), among the participants before the intervention is administered, will be equal between the groups, and that the only systematic difference at the group level will be the effect related to the difference in intervention. The flow diagram (figur 1) provides a schematic illustration of the design of the study.

The study design and interventions to be compared

The flow chart (figure 1) presents a schematic overview of the trial. The AWaC program is provided for the group that gets randomized to the intervention group. The intervention is based on councelling from a therapist (symptommestrende veiledning) for up to 15 sessions, with further follow-up from NAV and health services where needed. The intervention will include councelling on how the participant can handle and cope with symptoms of anxiety and depression that occur in a work context. If needed, they will also be offered assistance from an employment specialist to facilitate workplace adaptations or identification of appropriate employment. The therapeutic model proposes that the AWaC program mainly focuses on coping of symptoms in work situations, while the support from the employment specialist is focused on adaptation at the work place and finding a suitable job. The services provided from the employment specialist build on the IPS-model (individual placement and support), where a fast-track return to ordinary employment is a key feature. The integration between occupational services and symptom-directed councelling represents a unique approach for this target group. The services at the centres shall be low threshold, have short waiting lists, and have coping of work as an equal priority as improvement of mental health.

The group that is randomized to the control treatment will receive ordinary services from occupational services (NAV). The control condition is thus what can be described as “treatment as usual”, and represents the intervention the target group would have received had not the AWaC program been available. Participants allocated to this group will be sent confirmation of ordinary services from NAV or their primary physician, and the same confirmation will be sent to the local NAV office or the primary physician provided the participant consents to this. These participants will also receive some information and self-help resources such as recommended literature. Which services that in fact are available from NAV or the primary physician will vary across centres and will depend on local availability. Interventions and services provided for the control group will be registered through use of registry information and questionnaires.

Duration

The interventions, both the AWaC and TAU, are to be instigated as soon as possible after a person has completed randomization. The last follow-up of participants happens about a year after randomization. In addition, participants will be followed up with registry information on sickness absence and disability benefits over a period of four years.

Data registration

Data on individual characteristics, somatic and mental health as well as affiliation with work will be gathered through questionnaires at baseline and follow-ups at 6 and 12 months after baseline.

The following standardized questionnaires will be used:

The Hospital Anxiety and Depression Scale (HADS): Measures symptoms of anxiety and depression

EQ5D: Standardized tool to measure health outcomes after inteventions, both in terms of disability and quality of life. The cost-utility analyses will be based on this questionnaire.

Subjective health complaints (SHC): Measures prevalence of subjective health complaints.

Brief Illness Perception Questionnaire (BIPQ-R): Measures participants' perceptions of health, their causes and prognosis.

Eysenck personality questionnaire: Standardized measure of personality (neuroticism sub-scale).

Fatigue questionnaire: Measures physical and emotional fatigue.

TomCats: Measures coping.

Participants will also be asked about sex, age, level of education, marital status, number of children and caretaker obligations. Further, we will enquire on somatic conditions, previous treatment for mental illnesses and exposure for psychologic trauma. Participants will be asked about job satisfaction and degree of perceived

social support. Lifestyle factors will be measured though questions on perceived physical condition, use of alcohol and smoking, and subjective sleep quality will be registered. Participants will also be asked about their prognosis as in wether they expect to return to work or not.

Registry data:

The main outcome measure for the effect evaluation is information on degree of work participation and receipt of benefits or similar. Information about this will be gathered through use of registry information from NAV, supplied with information from registries on social services, income and job applications. Participants will also be asked to self-report their job status at 6 and 12 months follow-up.

Recruitment of participants

Those who will be included in the study will all be people who struggle with holding down a job because of common mental disorders. These persons will to a varying degree have other health problems, diagnoses and symptoms. The causes of their mental illness will vary and in most cases remain unknown. Although we will exclude those with an ongoing treatment in secondary mental health services, some of the participants will have had previous episodes of treatment for mental illnesses. There are few other scientifically rigorous studies of this important population with work related outcomes as the effect measure of interest. As embedded in the RCT-design, the control group will be recruited from the same population as the intervention group. Participants will mainly be recruited through referrals from NAV, primary care physicians and self-referrals.

Sample size

All the 6 centers in the country offering the AWaC program will during the trial periode be defined as a research project. That means that all those who are referred to, or self-refer, to the center in the trial periode, will be potential participants. The commissioning body has provided us with an estimate of 1000-2000 potential participants in the trial periode. An experimental design of this kind (randomized controlled trial), and of this size, will be expected to be sufficient to reveal a

statistically significant difference for the primary outcome between the AWaC program and control group, even for moderate effects. In other words, based on the numbers provided to us by the commissioning body, as well as standard estimates of necessary sample size, it should be possible to reveal intervention effects of a relevant magnitude, and this should also be possible for relevant sub-group analyses. Even with a smaller sample size, it will be possible to reveal relevant main effects.

Inclusion and exclusion criteria

Inclusion:

- Problems with work participation due to common mental disorders, primarily anxiety and depression
- People on sick leave or at risk of going on sick leave (should be about 50% of the study population), and people on long-term benefits (about 50%)
- Age: 18-60 years
- A motivation to return to/stay at work (defined as a willingness to start the work application process within 4 weeks for those on long-term benefits)

Exclusion:

- Other reasons as primary cause of work participation problems (e.g. somatic, social, economic and work-related)
- No motivation to work
- Serious psychiatric disorders
- Ongoing suicide risk
- Pregnant
- Ongoing psychotherapy
- Ongoing substance abuse problem
- NAV-employees

Recruitment procedures

Potential participants will arrive at the centres via several routes; referrals from primary care physicians, occupational health services, NAV, and to some extent self-

referrals. Inclusion and randomization must therefore be performed at the centres. This requires an initial meeting where those who arrive at the centres are informed about the project, and screened according to the inclusion and exclusion criteria. Those who fulfil the criteria will then be invited to participate and asked to sign the consent form. A separate manual for the initial meeting has been developed and is available as an appendix to this protocol. If the participant is set for participation, he or she will be asked to complete the baseline questionnaire. It is vital for the project that the person who carries out this initial meeting remains “neutral” towards the conditions in the intervention and control groups, and inform about these as conditions of equal worth. This is in contrast to how a clinician usually would carry out an initial meeting with a potential patient, as one of the goals of an initial meeting often will be to establish rapport with the patient and instill hope and optimism towards the treatment. To help the therapists remain more neutral than their natural inclination, we will make sure that the person who runs the first meeting by default never will act as the actual therapist for the same person should he or she later be randomized to the intervention.

After completing inclusion procedures, Uni Health will be provided needed details about the participant, and randomize the particiopants to either of the two conditions. Uni Health will send a letter back to the participant informing about the result of the random allocation. For the participants allocated to the control condition, the letter will also contain information about ordinary follow-up at NAV, in addition to information on self-help resources for people with mental illnesses (available as appendix). The participant is further encouraged to contact the local NAV office (in cases with more than 8 weeks sickness absence) or the primary physician (with less than 8 weeks of sickness absence) for further services there. Uni Health will also send a letter to the local NAV office or the primary physician informing about the allocation to the control condition, provided that the participant consents to this. For participants who are allocated to the intervention, the centres will get in touch with the participant for infomation about the allocation and time for the first appointment. Written informed consent must be signed before any procedures related to the study can commence.

Informational material

The following documents have been prepared for use in the trial:

- Referral letter to the GPs
- Referral letter to NAV
- Information letter to participants
- Informational brochure to potential participants
- Information to the NAV's website

Baseline questionnaire

The baseline questionnaire will be completed at the first consultation at the AWaC centre.

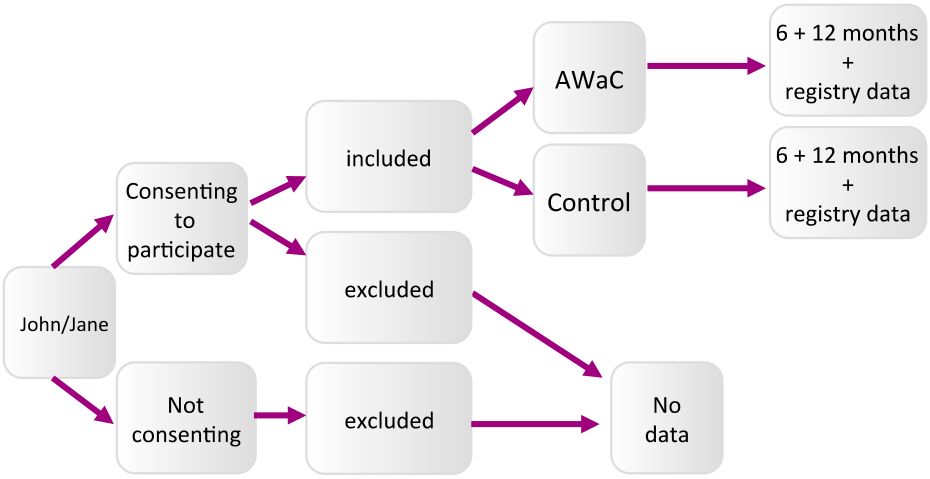
6-months questionnaire

At 6 months follow-up with a lighter questionnaire will be administered to the participants covering mental health, questions on work situations and participants' perceptions and impressions of the services they have received.

12-months questionnaire

At 12 months follow-up, the participants will receive a similar questionnaire as at 6 months. The exact design of the 6 and 12 months questionnaires will be developed and presented within September 2010.

Flow chart



Randomization procedure

A test technician at Uni Health (Nina Konglevoll) will conduct the randomization. The allocation will be stratified according to center (6 centres in total). The randomization will be based on a computer generated randomization list prepared by the trial statistician. Uni Health guarantees hidden randomization, which is the standard procedure at Uni Health. When a participant is recruited at one of the centres, information about the participant will be sent to Uni Health, and information about allocation will be sent back to the center by email or phone. The procedure at each center will therefore be as follows: After a participant has been recruited, informed about the study, and has given his/her informed consent to participate and has filled out the baseline questionnaire, the person in charge of the inclusion at the center will send en email to the test technician at Uni Health (nina.konglevoll@uni.no) in order to receive the information about which intervention the participant has been randomized to. The email will only include the following information about the participant: id-number, gender and age. The test technician will respond to the randomization email within 2 working days. If a participant is randomized to the AWaC group, the center where the participant was included will be in charge of the further follow up of the participant. If the participant is randomized to the control group, Uni Health will receive contact information to these participants by phone from the centers, and inform the participant about the allocation through a written letter that includes additional

information about available rehabilitation services and self-help resources. Information about allocation will also be sent to the participant's GP and/or case manager at NAV.

Based on previous experience, recruitment can be slow in the beginning of a trial this size. If the recruitment turns out to be too slow to meet the work capacity at the centres, an alternative randomization list with the ratio 1:2 can be applied. If this should be the case, the team leaders at the different center will contact the trial coordinator (Camilla Løvvik) to effectuate this.

The allocation codes of the randomization list, including details about block size etc, will be remained concealed from all researchers and clinicians until the recruitment, data collection and data analysis is completed.

Participants ID-numbers

The participants identification numbers will be a four digit number, where the first number is assigned after which centre the participant is rectuited from (Bergen 1, Trondheim 2, Tromsø 3, Østfold 4, Akershus 5 and Oslo 6), while the remaining three is given at order of inclusion (for example: the first participant recruited from Bergen will be given the ID number 1001).

No show at first consultation

The first time a participant fails to attend an appointment, the therapist will contact the participant directly via phone to ask what prevented them from coming, and dicsuss possible solutions with the participant. A new appointment is set up if possible. If the participant has chosen to withdraw from the study, this is to be registered on a designated dropout form (appendix).

Dropout and non-compliance

The therapists at the AWaC centers will contact the participant via phone to ask of they want to reveal why they want to withdraw from the study. If any reasons are presented, these are to be registered on the form (see copy of the dropout form in

the appendix). Reasons for dropout will also be communicated to the project group. The participant will be asked if he or she wants to stop attending sessions at the centre, or if he or she also wants to withdraw from further participation in the entire study including later follow-up measurements. Finally, the participant must be asked if already collected data can be used or if these are to be erased. In the latter case, this must be communicated to the project coordinator Camilla Løvvik in a separate email.

Included participants who drop out of the study will be analysed according to the intention-to-treat (ITT) principle.

Long-term follow-up

Participants will be asked for permission to follow them up in registry data for the next 5 years (until 2015) for information on sickness absence and work force participation.

Premature study closure

Premature study closure is not very likely in a trial that does not involve pharmaceutical or surgical interventions. If, however, it should turn out that one of the study arms of the AWaC trial shows consistent and reliable evidence of harm to the participants, the Trial Steering Committee will consider closing the trial.

Interim analyses

The commissioning body requires 3 preliminary reports during the project periode. One of those 3 (March 2012) will require an interim analysis of the 6-months results. It will also be considered whether further interim analyses will be necessary to assess whether a continuous randomization is acceptable.

Confidentiality

No identifying details about the participants will be used in any study database. The participants' names, addresses and other contact information will be kept at the centres for identification and treatment contact during the trial period.

Ethical considerations

All principles in the Helsinki-declaration will be followed. All participants will have capacity for consent, and consent will only be gathered after information about the project has been given. The participants will be allowed to withdraw from the study at any point, without having to present any reasons for this, and without this having any consequences for his or her further service delivery.

Ethical approval

The project was approved the 3rd of May 2010 by the Regional Committee for Medical Research Ethics, Western Norway (REK Vest).

Clinical Trial Register

The AWaC trial is registered in the international trial register: clinicaltrials.gov, and will be routinely updated as the study progress: https://register.clinicaltrials.gov/

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- Silje Endresen Reme (PhD, psychologist)
- Simon Øverland (professor, psychologist)
- Stein Atle Lie (professor, statistician)
- Camilla Løvvik (PhD-candidate, psychologist)
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- Thomas Lorentzen (PhD, sosiologist)

B: Dissemination protocol

The AWaC Trial

01.03.14

Title of the study:

A randomized controlled multicenter trial assessing the effect of the AWaC-program (At Work and Coping) for people with common mental disorders.

Funding source:

The trial is commissioned by the Norwegian Ministry of Health and Ministry of Labour, and financed through the National Strategy on Work and Mental Health (2007-2012).

Study numbers:

ClinicalTrials.gov Identification: NCT01146730

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1 GLOSSARY AND ABBREVIATIONS

AWaC	At Work and Coping (the intervention program)
CBT	Cognitive behaviour therapy
IPS	Individual Placement and Support
NAV	The Norwegian Labour and Welfare Administration
VR	Vocational Rehabilitation
GP	General Practitioner
Therapist	Everyone working with a therapeutic approach, regardless of profession
Employment Specialist	Everyone working with a work-focused approach (IPS) in the team
Client	Everyone receiving the AWaC service
Job search	Engagement of potential employers with regards to attaining paid jobs, and in some cases a time-limited traineeship

2 BACKGROUND

In 2007, the Norwegian Ministry of Labour and social inclusion and Ministry of Health and Care Services released a national strategy for work and mental health (2007-2012). The strategy called for novel approaches and services to increase people with mental health problems' participation in working life. One of the interventions that were funded through the national strategy was 3.1.c: At Work and Coping (AWaC). After an open call for tender, Uni Health was asked to carry out an experimental evaluation of the intervention. In this protocol, we will describe how the intervention was developed and the study carried out.

3 THE AWAC PROGRAM

3.1 Development and pilots

Prior to the AWaC model, it was generally recognized that many clients seen in rehabilitation services could have benefitted from treatment for mental health problems, but did not reach required clinical thresholds for access to specialized psychiatric treatment. There was a void between the need for services and capacity in the health services. Thus, it was decided to pilot the concept of an "at *work and coping team"* that could serve people with common mental disorders who were on sick leave or long-term benefits, with increased work participation as an explicit aim. A secondary aim of the pilot was to clarify the borders between supported employment administered through the Norwegian Labour and Welfare Administration (NAV). The first AWaC team started as a pilot in the Østfold region of Norway in 2006. The pilot protocol was strongly inspired by "Individual Placement and Support (IPS)", which at the time emerged as effective in helping people with severe mental disorders increase work participation. The main novelty of IPS was its explicit focus on getting people back into competitive work quickly, and the close collaboration between employement specialists and clinical therapists for each and every client. This approach was in stark contrast to the traditional model where the patient would be removed from work to receive treatment, and rehabilitated back to work upon remission. While there is a strong international literature in favour of IPS

for severe mental illness, this model had not been attempted in the context of common mental disorders.[1] The IPS model is based on 8 principles that guide the work-focused part of the treatment intervention. IPS is very specific and detailed regarding the employment specialists' methods. The lower degree of specification concerning what therapists do was addressed in the AWaC pilot, and cognitive behaviour therapy was chosen as the treatment approach. This decision was made primarily for two reasons: 1) cognitive therapy is a proven evidence based approach for anxiety and depressive disorders, and 2) the pilot had access to a systematic and well-developed educational program run by the Norwegian Association of Cognitive Therapy. We consider the specific definition of therapeutic approach to represent an elaboration of the IPS model. Combining IPS principles and cognitive behaviour therapy, and optimising the integration of therapy with an explicit work focus, makes the "AWaC model" uniquely innovative within the field of work and mental health. Building on positive experiences from the pilot, a decision was made to implement the project in 5 additional regions of Norway as stated in the National strategic plan for work and mental health, and evaluate the project through a multicenter randomized controlled trial. The following section specifies the AWaC model as it was applied in the six centres participating in the RCT.

3.2 SECTION 1 – THE IPS PRINCIPLES

Adherence to the 8 IPS principles underlines the explicit work focus in the AWaC model. In the following, we will describe key points for the principles and how this was implemented in the AWaC model. In cases where AWaC diverts from the IPS principles[2], we have explained how and why.

[1] Colloquial term for mild to moderate mental illnesses with high prevalence rates, such as anxiety disorders, depression and somatoform disorders.

[2] A "Fidelity Scale" has been developed to measure if IPS organisations actually follow the IPS principles. The scale has a scoring key from 1 to 5 within each principle. We will refer to this scale numerous times in this document. See www.attforingsbedriftene.no for a Norwegian translation of the fidelity scale".

3.2.1 Principle 1. Intake based on clients' desire to work

Target group specification for AWaC referrals:

- The person defines himself within the target group "common mental disorders", like anxiety and depressive disorders
- The person receives no other form of ongoing individual psychiatric treatment
- No active drug use
- No suicide risk
- The person perceives that reduced work participation is *primarily* due to mental health problems, not other difficulties like economic or social problems

Term clarifications

"Desire to work": Within the AWaC framework, «desire to work» is understood as a clearly expressed aim and ambision to achieve (re)employment within a set time frame. The time frame is set individually, but job searching should be initiated within 4 weeks.

Operationalization

The assessment session is a very important opportunity to investigate desire to work. One of the main topics of this session will be clients' work motivation. Aspects to cover:

- Is the desire to work truly the client's own, or is the client influenced by other peoples´ wishes/pressure?
- How does the client feel about initiating job search within 4 weeks?
- How motivated is the client to gain (re)employment?
- If the client seems very unsure; is he unsure about gaining (re)employment, or about type of profession, workload etc.?

The assessment session is conducted by the therapist. If there is considerable uncertainty regarding the client's desire to work, the employment specialist may participate in the session, or be consulted during or after the session.

Deviations from IPS:
The IPS model frames the principle as follows: *Intake is done based on the clients' choice (no exclusion criteria).* The AWaC trial adheres to the same principle, but aims for a different target group. While traditional IPS targets people with severe mental disorders, the AWaC trial targets people with common mental disorders.

3.2.2 Principle 2. Integration of Supported Employment and therapy

Term clarifications:
Integration: Within the AWaC framework, "integration" refers to the constant strive to combine therapy and an explicit work focus into one single process, and thus avoiding two parallel lines of action. People seeking AWaC services wish to gain (re)employment and cope better at work. This wish forms the basis of AWaC intake.

Another important aspect of integration is the employment specialists' and therapists' common understanding of the IPS model, and their common goal of collaborating to serve each client.

Operationalization and important principles necessary to achieve integration:

- Co-location

This is important in order to ensure collaboration and opportunities for meetings, both formally and informally. The teams can perform fast and continuous process assessments and swift interventions if needed. It is also our opinion that knowledge of team members' routines and face-to-face feedback contribute to the joint effort of serving clients.

The different teams have achieved co-location in different ways. In some regions the employment specialists are stationed in the same premises as the therapists, whilst

other regions practice co-location on certain days of the week. Others have scheduled routinely meeting appointments.

The teams also vary with regards to how the employment specialist positions are organised. Some teams have one employment specialist employed full-time, others have two specialists on part-time employment. Some have had less than one full-time employment specialist position due to lower caseloads.

According to the Fidelity Scale, one important predictor of achieving a high score on integration is the co-location and equal team participation of employment specialists and therapists.

There have been no official guidelines regarding the degree of AWaC affiliation for employment specialists, but the aim has been that the employment specialists' degree of co-location is informed by their AWaC client workload. This implies that employment specialists working full time with AWaC clients should be co-located full time at the AWaC office. Regarding teams with scheduled meeting appointments, it is recommended that therapists and employment specialists schedule at least one meeting per week[3].

- Clear allocation of roles and assignments between therapist and employment specialist: This is described in section 3.

- Joint plan of action for each individual client: This plan delivers guidelines for all team members.

- Joint reporting: This entails primarily writing a final report for the client's referrer at the point when the AWaC service has ended. As a general rule, therapists are only supposed to write a final report. So far, only the client's

[3] This is according to the Fidelity Scale. There have, however, in some teams been scheduled meetings once every other week. The purpose and content of the meetings have been individually considered.

referrer has received the final report, which in many cases will be their GP or occupational health care provider.

- Temporal integration: Therapy and job support are supposed to take place at the same time. We should avoid therapy and job search becoming two separate processes, or sequential processes.

Deviations from IPS

The AWaC teams differ from the traditional IPS teams in the following ways:

- AWaC employs the term "therapy" instead of "treatment", due to reasons detailed in section 2.
- AWaC does not employ treatment teams, but a "mini-team" consisting of a therapist and an employment specialist serving each individual client.
- The different team members keep separate clinical records.

3.2.3 Principle 3. The goal is competitive employment

Definition: «Competitive employment» means part- or full-time employment in positions that are available on the job market and paid normal wages.

This is an obvious principle in AWaC because paid labour enhances integration, self-image and mental health. Thus, the goal to achieve paid labour is a prerequisite for AWaC intake. Further, a consistent finding in the IPS literature is the prominence of "place and train"[4] compared to "train and place" in terms of employment rates.

Operationalization – how to implement principle 3

- Employment specialists engage potential employers with the prospect of employment for IPS clients
- They make contact with and address employers with an actual need of labour

[4] "Place and train" refers to education and occupational training being done at the workplace, as opposed to «train and place», which constitutes vocational training in sheltered workshops prior to ordinary employment in the form of either competitive employment or traineeship.

- They offer support for both employers and clients
- Traineeship is to be used only in special cases. Traineeships should not last longer than 12 weeks, and its purpose is to:
    - find out whether the job «matches» the client
    - identify needs for individual adaptations at the workplace
    - gain experience within a new profession

  A detailed plan must be designed that explicitly states the conditions and purpose of the traineeship.
- An especially important principle in the IPS model is that clients are offered support also after they gain employment. This goes for both employees and employers. Support can also be given after the probation period has ended and the client is fully employed.

  Support is usually more extensive at the start of the AWaC service. Support may be given in several forms, and at lower intensities if needed (by phone, e-mail, text messages etc.). Generally speaking, clients are rarely in contact with their employment specialist for periods longer than one year.

Deviations from IPS:

The AWaC model deviates somewhat from the IPS model as it opens for the use of time-limited traineeships (a maximum of 12 weeks). The reason for this is that the Norwegian job market is characterised by a rather high threshold to enter, and few low-threshold jobs compared to other countries. The Norwegian job market is also characterised by extensive use of lengthy traineeships in ordinary companies. Many employment specialists are under the impression that employers expect traineeships to be clients' «service of choice» instead of competitive employment. Traineeships and other measures like wage subsidies can in some cases be necessary in order to gain acceptance from an employer. However, we strive to minimise the use of such measures when engaging potential employers with the aim of always trying to achieve competitive employment before traineeships are initiated.

3.2.4 Principle 4. Individualised work incentives planning

AWaC therapists are expected to have general knowledge of the public insurance system. Nevertheless, NAV counsellors are still the public insurance experts, and can probably provide the best counselling regarding this. Hence, the most important task for therapists and employment specialists is to ensure that the client receives adequate counselling regarding existing benefits and their potential consequences with regards to employment. More specifically, the AWaC team shall establish correspondence between clients and their NAV counsellor, and if needed attend meetings where benefits are discussed.

Deviations from IPS

The fact that the AWaC team does not possess the required qualifications to perform the individualised planning and/or does not perform this service is a deviation from the Fidelity Scale. It is still our opinion that the work incentives planning principle is fulfilled, as the client is provided with such counselling. The various NAV offices may vary within and across regions with regards to the type of counselling clients receive, and the advices they are given. This emphasises the importance of the teams having general knowledge of the public insurance system provided by NAV. A potential solution may be to have one person affiliated with the team who possesses the required qualifications to perform individualised planning. Another solution, that would enhance our intake procedure and collaboration with local NAV offices, would be to appoint one counsellor who is to serve all AWaC clients within each region. Both these solutions would ensure continuity of the individualised planning service.

3.2.5 Principle 5. Rapid search for competitive jobs

Job search entails the engagement of potential employers with regards to attaining paid jobs, and in some cases a time-limited traineeship.

In some cases we have chosen to define job-related activities as part of the job searching process. This can be career counselling, contacting relevant employers, and making visits to get information about various professions and necessary qualifications, writing and updating CVs, or obtaining certificates from former

employers. Such activities contribute to an explicit work focus and how to gain (re)employment.

The explicit work focus is central from the start of the AWaC service, and an important topic to be covered in the first session. Principle 5 entails that the job search is initiated within 4 weeks in order to maintain progress and client motivation to work. This is particularly important for clients who are unemployed.

Deviations from IPS
None.

3.2.6 Principle 6. Continuing, time-unlimited follow-up

Definition of time-unlimited follow-up at AWaC: Clients can contact their therapist if needed for a period of one year after terminating the official use of the AWaC service. Clients are informed about this at the time of termination.

If a case is re-opened, a limit is set to a maximum of 5 therapy sessions. The duration of follow-up from employment specialists is assessed individually. The maximum follow-up period is 3 years.

Employments specialists' workload is approximated to 20 clients per full-time position. This may vary according to, among other things, the complexity of a given caseload. Some teams have a caseload of up to 25 clients.

Generally speaking, only short-term follow-up is requested when employers contact us after service termination. A final report is written which includes evaluations from both the therapist and the employment specialist. This points to the importance of close collaboration within the team.

Deviations from IPS

The definition of «continued, time-unlimited follow-up» may seem somewhat narrow, but the Fidelity Scale also involves guidelines for gradual termination of follow-up. It is our opinion that the principle of enabling client autonomy is the most important. However, all clients are provided with the type and duration of follow-up they ask for. As such, there are no deviations from principle 6 as implemented in the AWaC service.

3.2.7 Principle 7. Clients' preferences are important

Job search in the IPS model is based on clients' own preferences. Rather than focusing on available jobs found on the job market or through the employment specialists' network, clients' individual preferences and goals are prioritised when searching for jobs. Clients' preferences is a crucial principle within both the IPS and the AWaC framework, and is considered to be the most favourable and effective approach when it comes to finding the right kind of jobs and keeping them.
Within the AWaC framework, clients' preferences constitute the basis for the collaboration between the employment specialist, therapist and client. Preferences are addressed as soon as possible, and discussed based on the various factors (health-related, social, economic etc.) with the aim of fulfilling the clients' wishes.
A plan of action is designed that states the various steps that is needed to achieve the client's goals, and which team members are responsible for performing each step.

Deviations from IPS:

None. However, we are aware that some aspects of the NAV regulations may run contrary to this IPS principle. To exemplify, one has to abandon the principle of "adequate/appropriate employment" related to work assessment allowance, which requires the client to accept any type of job that is available. Local job availability also represents a potential limitation to the fulfilment of clients' wishes, and should be discussed within the team.

3.2.8 Principle 8. Systematic job development/support

Employment specialists are to develop systematic employer networks based on clients' preferences, and establish correspondence with local employers based on systematic contact.

Steps for establishing contact with employers/companies

We have built on a model from Sussex Partnership in England, which describes the various steps:

Step 1 – preparing for meetings

- Get to know the employer of interest; through web pages and visits
- Talk to reception desk staff to get further information
- Ask to talk to the person in charge of recruitment
- Be specific about what you want to gain from the meeting
- Respect the other person's schedule
- Show knowledge and understanding of the employer's company

Step 2 – meeting with the employer/chief of recruitment

- Do they experience any challenges with regards to recruitment?
- Do they have jobs available, and if so, what kind of jobs?
- What is the main service/product offered by this company?
- Which central characteristics do their most valued employees possess?
- Give information about the AWaC service, and try to normalise mental health problems. Give only information if asked to – the primary goal is to attain information about the employer.

Step 3 – engaging the employer/chief of recruitment

a) If you have a potential client in mind; give a short presentation of the candidate, CV if available and other relevant information
b) If you do not have a client in mind; keep in touch with the employer by phone or mail/e-mail

c) If there are no jobs available; ask if the client you have in mind can visit and have information about the company and the qualifications required to work within this field.
   If needed, the employer/chief of recruitment can contact other companies affiliated with AWaC to get more information about the AWaC service.

3.3 SECTION 2 – COGNITIVE WORK COPING WITHIN AWaC

3.3.1 Symptom coping counselling and cognitive work coping

The therapeutic method used in AWaC was at the initiation of the Østfold pilot in 2006 described as ”symptom coping counselling”, but was redefined as ”cognitive work coping” or “work-focussed CBT” when the model was implemented in the 5 additional regions in 2008. This was done because of the final decision to base the therapeutic interventions on CBT.

Whilst employment specialists utilise the IPS principles in their day-to-day practice, therapists use a cognitive therapeutic approach in their client sessions. The IPS principles are always present as a backdrop, especially with regards to the principle of integration. However, therapists attain their therapeutic tools primarily from their specialisation in cognitive therapy and its principles (which are described below). ”Cognitive work coping” gives a more specific and elaborate description of the AWaC method, which in addition to focusing on symptoms, emphasises that the therapy session has a cognitive approach. The term specifies two important aspects. Firstly, symptoms are understood within a cognitive framework and addressed by using cognitive therapeutic interventions. Secondly, the main focus of therapy is coping at work.

3.3.2 Counselling, therapy or treatment?

We have chosen to refer to the sessions provided by the AWaC therapists as ”therapy”. The use of this term is debatable, but it seems to give the best description of the content and quality of the sessions. Describing the therapy sessions as

”counselling” (as in the original term ”symptom coping counselling”) seems to be too narrow and superficial, whilst the term ”cognitive work coping” is associated with cognitive therapy, and is thus a more fitting term. It is still worth pointing out that the therapy sessions offered in AWaC does not formally qualify as treatment. This would entail a much more comprehensive health care service based on thorough diagnostic assessment. Our approach is characterised by directly addressing symptoms and daily functioning, and the client´s coping ability related to this.
The debate regarding the use of the terms ”therapy” versus ”counselling” may seem artificial as long as therapists are comfortable with the chosen methods and their professional role at AWaC. The dilemma stems from the fact that NAV is not supposed to offer treatment, and that both treatment and therapy seems to ”belong to” the health care system. An agreement that”cognitive work coping” involves work coping and symptom management based on cognitive behaviour therapy, was acceptable to both the clinicians and NAV.

It is worth noticing that the English literature on IPS uses the term ”counselling” rather than ”therapy” when referring to the therapists´ practice. It is, however, unclear what type of education the therapists have in this case, and what kind of therapeutic approach that is used.

3.3.3 “Work coping”

The desire to address work and work participation in some form of therapy or counselling has been the driving force behind the initiation of AWaC. ”Coping”, which in this case is defined as ”the ability to control one´s own performance on a given task[5]”, indicates that something needs to be practiced, or put into action. Hence, cognitive behaviour therapy is a very well suited method within this context, as it employs homework assignments that could and should be tested in the workplace, and acknowledges the importance of practice and giving it time. The term ”*work* coping” points to the importance of using work participation as a tool in

[5] The definition of ”coping” is derived from the term ”self- efficacy”, which Bandura (1977) defined as ”believing in the ability to control one´s own performance on a given task”.

the therapeutic process, delineates our target client group (those that have or are about to attain a job), and signals to potential clients that work will be an prioritized topic in the therapy sessions, and often the most important topic.

3.3.4 Cognitive behaviour therapy

The cognitive behaviour therapy offered in the AWaC followed from these principles and characteristics[6]

- Mental health problems are characterised by negative assumptions, thoughts and images. The client is made aware of these thoughts and assumptions and their consequences through therapy
- Healthy functioning and mental disorders exist on a joint continuum
- Normalisation of symptoms and psychoeducation is emphasised, on the basis of recent psychological research
- Therapy is based in the client´s appraisal of the situation
- The therapist-client working alliance is of significance
- Skilled therapists are perceived as empathic, attentive, understanding and competent
- One seeks to support the client´s ability to cope with problems and change dysfunctional thoughts and behaviours. This entails helping the client gain a more open and exploratory attitude towards life and his own thoughts and appraisals. A good session provides both belief in the prospect of change, and the courage to make the change
- The therapist usually takes active part in the conversation, communicates in a clear and unambiguous way and acts in a sympathetic and friendly manner
- The client´s engagement in and commitment to therapy is crucial to attaining a positive therapeutic outcome
- The best form of therapy is characterised by active collaboration aimed at achieving clearly defined goals

[6] Essensials derived from the Norwegian Cognitive Therapy Foundation homepage

The principles and characteristics were integrated and operationalized through practical work to target cognitive work coping in real-life situations

- Work and topics related to work participation and coping are addressed in each session
- Examples from clients´ daily lives, which is an integral part of cognitive therapy (ABC model, case formulation), are usually drawn from real or imagined work situations
- Homework assignments are relevant for and/or is thought to enhance functioning at work, and prepare the client for (re)employment
- When needed, the therapist initiates collaboration with other agents relevant for the client´ functioning at work, like their Inclusive Working Life agent, general practitioner, employer, occupational health care etc. The threshold for taking such initiative is low, and it should always be done in agreement with the client. The therapist is supportive, but it is always best if the client can fix the problem on his own. This is in line with the cognitive therapeutic principle of emphasising patients´ engagement and involvement in order to both achieve a positive therapeutic outcome, and to enhance coping and perceived control in clients
- Team meetings with clients, therapists and employment specialists are scheduled as soon as the therapist and client have concluded that job support services are needed
- Team meetings are scheduled when one or more team members want to, typically at times when there have been important changes with regards to the client´s work situation or mental health
- Co-location allows for informal communication and distribution of information and updates regarding clients and possible candidates, in addition to enhancing a joint professional understanding of the therapeutic approach and clients' needs

3.4 SECTION 3 - ORGANISATION AND DISTRIBUTION OF ROLES

3.4.1 Anchoring within the NAV organisation

AWaC belongs administratively and organisationally to a special division within NAV. The leadership is provided through the coordinator at the Norwegian Labour and Welfare Ministry. Employment specialists are employed in VR enterprises where a number of their case load are reserved for AWaC clients. There is some variation across regions with regards to employment specialists´ affiliation with AWaC. Some regions have one full-time employment specialist position while others have two half-time positions.

3.4.2 The teams

The AWaC teams consist of a team leader, therapists and employment specialists.

- The *team leader* is ideally a psychologist. In some cases team leaders can have a bachelor´s degree in health and social services, a minimum of basic cognitive therapy training from the Norwegian Association of Cognitive Therapy, and has considerable experience working with AWaC or other services within the work and mental health field.
- *Therapists* in the team are either psychologists or have a bachelor´s degree in health and social services and a minimum of basic cognitive therapy training from the Norwegian Association of Cognitive Therapy. The number of therapists in each team varies across regions.
- *Employment specialists*. There should be a minimum of one full-time position in each team, alternatively two half-time positions. Employment specialists are required to have relevant qualifications and broad experience with Supported Employment, and extensive knowledge regarding the IPS principles and the job market in the team´s region.

When it comes to co-location and how team members collaborate, we also refer to IPS principle 2 in section 1, which addresses the integration of job support and therapy.

3.4.3 Distribution of roles within AWaC

- *Team leader:*
    - Intake coordination – both assessment sessions and distribution of clients
    - Responsible for coordinating the distribution of information to referral agents
    - Participate in AWaC team leader meetings
    - Coordinating the professional updating within the team
    - Coordinating supervision within the team
    - Organising and leading team meetings
- *Therapists:*
    - Conducting therapy sessions focusing on coping with symptoms, and using the work situation as an arena for training and coping
    - Conducting assessment sessions
    - Responsible for client intake to employment specialists
    - Final reports to referral agents in cases where the client has not used the employment specialist service

All items regarding therapists´ tasks also apply to team leaders.

- *Employment specialists*
    - Career mapping and counselling
    - Job support sessions with clients
    - Helping clients find, attain and keep jobs
    - Direct contact with employers
    - Negotiating wages
    - Responsible for maintaining an explicit work focus during team meetings

- *Joint responsibility*
    - Writing plans of action and aims for the team collaboration

- Distributing important information regarding single cases within the team
- Collaborating with relevant external agents
- Participate in dialogue meetings and other meetings regarding the client
- Final report

3.4.4 External collaborators

VR enterprises often refer potential clients to AWaC. In such cases, the employment specialist at the given enterprise will be the natural AWaC collaborator. It is to be expected that this employment specialist follows the ”traditional” supported employment methods to a greater extent. This does not, however, contradict the IPS principles with regards to close collaboration, the distribution of roles and tasks, and striving for rapid job search, and is therefore not expected to pose a problem.

4 PRIMARY AIM OF THE STUDY

A coordinated and integrated intervention program has been lacking for people who struggle with work participation due to CMDs, and the AWaC program was developed to address this shortcoming. The primary aim of the study was to investigate if the AWaC program led to increased work participation for people with CMDs compared to treatment as usual.

4.1 Primary outcome measures

The primary outcome was operationalized as increased employment at 12-months follow-up. This involves maintained work participation, new employment, or a full or partial return to work. Full or partial return to work was further operationalized as working and no reception of health or work-related benefits, or reduced benefit coverage and increased work participation compared to baseline status.

4.2 Secondary outcome measures

The secondary outcome measures included validated measures of mental health (Zigmond & Snaith, 1983) and health-related quality of life (The EuroQol Group, 1990). See further description of the questionnaires below.

5 SECONDARY AIMS

The secondary aims of the study included the following:

1) Evaluate the effect of the AWaC program on mental health and quality of life. See description of how this was measured under *data registration* below.
2) Conduct a cost-benefit evaluation based on the effects demonstrated on work participation in the trial period. The economic returns of the intervention (AWaC) compared to the control condition was calculated by using a standard cost-benefit formula based on the human capital approach (Berkowitz, 1988; Haveman, Halberstadt, & Burhauser, 1984; Risa, 1997).
3) Evaluate potential sub-group effects of the AWaC program. To test the effectiveness of the intervention in an ecologically valid sample, we aimed to include a diverse group of participants in order to investigate sub-group results defined by work status.
4) Conduct a systematic analysis of how the AWaC program was implemented and collaborated with the social insurance system and the primary health care system. The aim of this analysis was to identify organizational challenges and solutions to obtain a more integrated and coordinated service for the individual user of the AWaC program. This part of the study was conducted as a qualitative study involving interviews with responsible stakeholders (team leaders and therapists at the centres, collaborating institutions and user representatives).

6 STUDY DESIGN AND INTERVENTIONS

The effect evaluation of the AWaC program offered at the centres was carried out as a randomized controlled multicentre study. Employing an experimental design (RCT) will in most cases mean that the effect of the intervention is identified by comparing results between one or more intervention groups and one or more control groups. With an adequate number of participants, one can assume that differences, both known (observed) and unknown (unobserved), among the participants before the intervention is administered, will be equal between the groups, and that the only systematic difference at the group level will be the effect related to the difference in intervention.

The AWaC trial is also a pragmatic trial. Pragmatic trials are designed to measure effectiveness, which involves investigating whether an intervention works in usual conditions of care. This means that one must include participants who are likely to be offered the intervention outside the trial, and balance the inclusion/exclusion criteria thereafter. This is to ensure applicability, or generalizability, in a wide range of usual care settings (Zwarenstein et al., 2008). The AWaC trial was commissioned by the Norwegian health and welfare authority, which specifically asked for an experimental evaluation of an intervention scheme (AWaC) in a real world setting. The completion of this trial can thus have policy implications through demonstrating the utility of trials in this sector, and help reduce the gap between policy and research.

6.1 Interventions to be compared

The AWaC program is provided for the group that gets randomized to the intervention group. The intervention is based on work-focused CBT from a therapist for up to 15 sessions, with further follow-up from NAV and health services where needed. The intervention includes councelling on how symptoms of anxiety and depression that occur in a work context can be handled and coped with. For those in need of individual job support (primarly participants on long-term disability), assistance from an employment specialist was offered to facilitate workplace

adaptations or identification of appropriate employment (see chapter 3 for detailed description of the AWaC program). Patients allocated to the control group received ordinary services from the complete menu NAV and the GP have at their disposal, including referral to other health professionals and rehabilitation services. The control group also received a letter where they were encouraged and informed about available services and self-help resources. The control condition thus represents an active control condition. Which services that in fact are available from NAV or the GPs vary across centres and depend on local availability. This information was therefore registered through use of registry information and questionnaires.

The interventions, both the AWaC and control condition, were instigated as soon as possible after randomization. Participants were followed-up with questionnaires 6 and 12 months post baseline and followed up with registry information on sickness absence and disability benefits over a period of five years.

7 DATA REGISTRATION

Data on individual characteristics, somatic and mental health as well as affiliation with work were gathered through questionnaires at baseline and follow-ups.

7.1 Standardized questionnaires

- *The Hospital Anxiety and Depression Scale (HADS):* Measures symptoms of anxiety and depression (Zigmond & Snaith, 1983) and is widely used in both the general population and various patient populations (Bjelland, Dahl, Haug, & Neckelmann, 2002). A cut off score of ≥8 on both subscales has been found to give an optimal balance between sensitivity and specificity (approximately 0.80 for both subscales) according to DSM-III, DSM-IV, ICD-8, and ICD-9 (Bjelland et al., 2002).
- *EQ5D*: Standardized tool to measure health outcomes after inteventions, both in terms of disability and quality of life (The EuroQol Group, 1990).

The health index from EQ5D was used to measure health-related quality of life.

- *Subjective health complaints (SHC):* Measures prevalence of subjective health complaints. The SHC inventory consists of 29 questions concerning severity and duration of common health complaints (Eriksen, Ihlebaek, & Ursin, 1999).
- *Brief Illness Perception Questionnaire (BIPQ-R):* Measures participants' perceptions of health, their causes and prognosis (Broadbent, Petrie, Main, & Weinman, 2006).
- *Eysenck personality questionnaire:* Standardized measure of personality (neuroticism sub-scale).
- *Fatigue questionnaire:* Measures physical and emotional fatigue and was measured by the 11-item Chalder Fatigue Questionnaire (CFQ) (Chalder et al., 1993).
- *Coping:* Was measured by the Theoretically Originated Measure of the Cognitive Activation Theory of Stress (TOMCATS) (Odeen et al., 2012).

Participants were additionally asked about gender, age, level of education, marital status, number of children and caretaker obligations, as well as somatic conditions, previous treatment for mental illnesses and exposure for psychologic trauma. They were asked about job satisfaction and degree of perceived social support, and lifestyle factors were measured though questions on perceived physical condition, use of alcohol and smoking, and subjective sleep quality. Lastly, participants were asked about their self-rated prognosis regarding return to work or not.

7.2 Registry data

The main outcome measure for the effect evaluation is degree of work participation. Data from the national social insurance register (start-and stop dates for payment of various social insurance benefits) and the national employee-register (start- and stop-dates for jobs, and an indicator for part-time or full time work) provides information to determine if a person is in regular work or not in each calendar month after inclusion in the study. We can thereby, with no loss to follow-up,

determine if participants i) are in regular work, part time or full time, and not receiving benefits of any kind, ii) combines work and recipient of benefits (typically 50% disabled, usually working 50% of full time and having the corresponding income loss compensated by social insurance benefits, and iii) is out of work, with or without social insurance benefits, the latter depending on entitlement to benefits. This information was collected for each month of follow-up.

7.3 Long-term follow-up

The study approval and consent allows registry follow-up up through 2015 for information on sickness absence and work force participation in a long-term perspective.

8 SAMPLE SIZE

All the 6 centers in the country offering the AWaC program were during the trial periode defined as a research project. That means that all those who were referred to, or self-referred, to the center in the trial periode, were potential participants. The commissioning body provided us with an estimate of 1000-2000 potential participants in the trial periode. An experimental design of this kind (randomized controlled trial), and of this size, were considered to be sufficient to reveal a statistically significant difference for the primary outcome between the AWaC program and control group, even for moderate effects. Based on an optimistic 10% effect difference in favour of AWaC vs. control (50% versus 40% increased work participation), we calculated that a sample size of 388 in each group would be sufficient to detect statistically significant results. We also calculated obtainable differences based on a sample size of 600 in each group where a difference of 8% (48% versus 40%) would yield statistically significant differences.

9 INCLUSION AND EXCLUSION CRITERIA

9.1 Inclusion

- Problems with work participation due to common mental disorders, primarily anxiety and depression
- People on sick leave or at risk of going on sick leave, and people on long-term benefits
- Age: 18-60 years
- A motivation to return to/stay at work (defined as a willingness to start the work application process within 4 weeks for those on long-term benefits)

Both *at risk of going on sick leave* and *motivation to return to/stay at work* were defined by the patients, i.e. through self-report and self-referrals. The justification for this is the previous demonstration of patients' risk assessments being more accurate than disorder-related factors (e.g. Nieuwenhuijsen, Verbeek, de Boer, Blonk, & van Dijk, 2006).

9.2 Exclusion

- Other reasons as primary cause of work participation problems (e.g. somatic, social, economic and work-related)
- No motivation/desire to work
- Serious psychiatric disorders
- High suicide risk
- Pregnant
- Current substance abuse problem
- Ongoing psychotherapy

Patients with a past therapy were not excluded, only people who at the time of the initial screening received on-going, weekly therapy. This was due to ethical considerations: As the work-directed approach is not commonplace (hence the need for this trial), engagement in other therapy elsewhere could mean patients would

receive confusing and mixed messages that could be negative for the patients and their prognosis.

During the first assessment of enrolment, a clinical psychologist assessed the presence of CMDs, severe psychiatric disorders or substance abuse.

10 RECRUITMENT PROCEDURES

Those who were included in the study were all people who struggled with holding down a job because of CMDs. As embedded in the RCT-design, the control group were recruited from the same population as the intervention group. Participants were mainly recruited through referrals from NAV, GPs and self-referrals. Inclusion and randomization were therefore performed at the centres. This required an initial meeting where those who arrived at the centres were informed about the project, and screened according to the inclusion and exclusion criteria. Those who fulfilled the criteria were then invited to participate and asked to sign the consent form. If the participant were set for participation, he or she would be asked to complete the baseline questionnaire. It was stressed that the person who carried out this initial meeting remained “neutral” towards the conditions in the intervention and control groups, and informed about these as conditions of equal worth. This is in contrast to how a clinician usually would carry out an initial meeting with a potential patient, as one of the goals of an initial meeting often will be to establish rapport with the patient and instill hope and optimism towards the treatment. To help the therapists remain more neutral than their natural inclination, we made sure that the person who ran the first meeting by default never acted as the actual therapist for the same person should he or she later be randomized to the intervention.

10.1 Informational material

The following documents were prepared for use in the trial:

- Referral letter to the GPs
- Referral letter to NAV

- Information letter to participants
- Informational brochure to potential participants
- Information to the NAV's website

11 RANDOMIZATION PROCEDURE

A test technician at Uni Health conducted the randomization. The allocation was stratified by centre (6 centres in total) for administrative purposes, as well as to prevent a skewed randomization. The randomization was based on a computer generated randomization list prepared by the trial statistician. Uni Health guarantees hidden randomization, which is the standard procedure at Uni Health. When a participant was recruited at one of the centres, information about the participant was sent to Uni Health, and information about allocation were sent back to the center by email or phone. The procedure at each center was therefore as follows: After a participant had been recruited, informed about the study, and had given his/her informed consent to participate and filled out the baseline questionnaire, the person in charge of the inclusion at the center sent en email to the test technician at Uni Health in order to receive the information about which group the participant had been randomized to. The email would only include the following information about the participant: id-number, gender and age. The test technician would respond to the randomization email within 2 working days. If a participant were randomized to the AWaC group, the center where the participant was included would be in charge of the further follow up of the participant. If the participant were randomized to the control group, Uni Health would receive contact information to these participants by phone from the centers, and inform the participant about the allocation through a written letter that included additional information about available rehabilitation services and self-help resources. Information about allocation was also sent to the participant's GP and/or case manager at NAV.

From our previous experience with clinical trials, we know that recruitment can be slow in the beginning of a trial this size. It was therefore decided that if the

recruitment turned out to be too slow to fill the work capacity at the centres, an alternative randomization list with the ratio 1:2 would be applied.

The allocation codes of the randomization list, including details about block size etc, remained concealed from all researchers and clinicians until the recruitment, data collection, and data analysis were completed.

11.1 Participants ID-numbers

The participants identification numbers had four digits, where the first was assigned according to which centre the participant was rectuited from (Bergen 1, Trondheim 2, Tromsø 3, Østfold 4, Akershus 5 and Oslo 6), while the remaining three were given at order of inclusion (for example: the first participant recruited from Bergen was given the ID number 1001).

12 NO-SHOW, DROPOUT AND TREATMENT ADHERENCE

12.1 No show at first consultation

The first time a participant failed to attend an appointment, the therapist would contact the participant directly via phone to ask what prevented them from coming, and discuss possible solutions with the participant. A new appointment was set up if possible. If the participant chose to withdraw from the study, this was registered on a designated dropout form.

12.2 Study dropout

The therapists at the AWaC centers called participants who dropped out from the intervention and asked if they wanted to share their reasons for withdrawal. If any reasons were presented, these were registered on the dropout form. The participants were asked if they wanted to stop attending treatment sessions, or they also wanted to withdraw from further participation in the study, including later follow-ups. Finally, the participant was asked if already collected data could be used

or if these had to be erased. The project coordinator was informed and made sure data were erased upon such requests.

12.3 Treatment adherence

Participant who dropped out of treatment were defined as a dropout if they received less than 3 treatment sessions. Treatment adherence in the control group was not registered.

The analysis conformed to the intention-to-treat (ITT) principle and participants who dropped out of the study were analysed according to allocation at baseline. For the primary outcome, based on complete registry data, there was no missing data at follow-up. For the secondary outcomes, inverse probability weighting on observed baseline characteristics was used to compensate for possible selective loss to follow-up.

13 PREMATURE STUDY CLOSURE

We did not consider premature study closure to be very likely in a trial that does not involve pharmaceutical or surgical interventions. If, however, it should turn out that one of the study arms of the AWaC trial would have shown consistent and reliable evidence of harm to participants, the Trial Steering Committee would have considered terminating the trial.

14 INTERIM ANALYSES

The commissioning body required 3 preliminary reports during the project period. For the third preliminary report (March 2012), the commissioner also required an interim analysis based on results at 6-months follow-up. If the interim analysis had demonstrated major positive effects of the intervention, or major negative effects of the control condition, with strong statistical significance, the Trial Steering Committee would have considered trial termination according to research ethics guidelines.

15 CONFIDENTIALITY

No identifying details about the participants were part of any study database used for analysis. The participants' names, addresses and other contact information were kept at the centres for identification and treatment contact during the trial period in line with normal routines.

16 ETHICAL CONSIDERATIONS

All principles in the Helsinki-declaration were followed. All participants had capacity for consent, and consent was only gathered after information about the project had been given. The participants were allowed to withdraw from the study at any point, without having to present any reasons for this, and without this having any consequences for his or her further service delivery.

16.1 Ethical approval

The project was approved the 3rd of May 2010 by the Regional Committee for Medical Research Ethics, Western Norway (REK Vest).

17 CLINICAL TRIAL REGISTER

The AWaC trial was registered in the international trial register: clinicaltrials.gov, and will be routinely updated as the study progresses: https://register.clinicaltrials.gov/

18 REFERENCES

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