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The Danish national return-to-work program – aims, content, and design of the process and effect evaluation

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The Danish national return-to-work (RTW) program aims to improve the management of municipal sickness benefit in Denmark. A study is currently ongoing to evaluate the RTW program. The purpose of this article is to describe the study protocol. The program includes 21 municipalities encompassing approximately 19 500 working-age adults on long-term sickness absence, regardless of reason for sickness absence or employment status. It consists of three core elements: (i) establishment of multidisciplinary RTW teams, (ii) introduction of standardized workability assessments and sickness absence management procedures, and (iii) a comprehensive training course for the RTW teams. The effect evaluation is based on a parallel group randomized trial and a stratified cluster-controlled trial and focuses on register-based primary outcomes – duration of sickness absence and RTW – and questionnaire-based secondary outcomes such as health and workability. The process evaluation utilizes questionnaires, interviews, and municipal data. The effect evaluation tests whether participants in the intervention have a (i) shorter duration of full-time sickness absence, (ii) longer time until recurrent long-term sickness absence, (iii) faster full RTW, (iv) more positive development in health, workability, pain, and sleep; it also tests whether the program is (v) cost-effective. The process evaluation investigates: (i) whether the expected target population is reached; (ii) if the program is implemented as intended; (iii) how the beneficiaries, the RTW teams, and the external stakeholders experience the program; and (iv) whether contextual factors influenced the implementation.

The program has the potential to contribute markedly to lowering human and economic costs and increasing labor force supply. First results will be available in 2013. The trial registrations are ISRCTN43004323, and ISRCTN51445682.

Key terms Denmark; design; economic evaluation; intervention; long-term sickness absence; organizational change; process evaluation; sickness absence; work resumption.

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Sickness absence and work disability put a considerable strain on public finances. Concerns about the level of sickness absence have been growing among policy-makers in many western countries. In 2008, the annual level of sickness absence in Denmark corresponded to approximately 5% of the workforce and reimbursement costs per year were estimated to be around 5 billion euro – not including healthcare costs or loss of productivity (1). Reducing long-term sickness absence and work disability is likely to lower public spending. Moreover, promoting labor market participation is essential for Denmark and other European countries that face a decline in the proportion of residents in the working age due to an aging workforce (2). Finally, promoting labor market participation contributes to social inclusion and reduces the risk of poverty for the sick-listed person (3).

Promoting a faster and more sustainable return to work (RTW) after long-term sickness absence can be a challenging task. A person's chance of returning to the labor market is not solely determined by improvement in health, but is also affected by individual factors (ie, sociodemographic and psychological characteristics) and factors from the workplace, health, and social insurance domains (4). RTW is also influenced by national sickness benefit policies and the economic situation in general (3, 5, 6). Furthermore, the transition from long-term sickness absence to work is often a complex process involving various stakeholders (ie, the affected workers, employers, healthcare providers, and insurers), who may have different perspectives on how to achieve a successful RTW (7). According to current ecological models of RTW, prolonged absence from work is often the result of inadequate and ineffective cooperation between these stakeholders (5, 8). A Swedish randomized-controlled trial (RCT) showed that lack of cooperation between stakeholders was responsible for about 75% of the total social security expenditures (9). Hence, interventions to promote RTW need to take into account the complex interplay between stakeholders (10). The guideline of the British National Institute of Clinical Excellence (NICE) on long-term sickness absence and incapacity points to early, multidisciplinary, and workplace-based interventions as the most likely ones to create positive results (11). Based on a systematic literature review (12), the Institute for Work and Health in Toronto, Canada, recommends interventions including a designated RTW coordinator responsible for: (i) identifying barriers to RTW, (ii) developing solutions to overcome these barriers, (iii) keeping the RTW plan on track, and (iv) obtaining support from healthcare providers and employers.

To reduce sickness absence and improve labor market participation, the Danish government launched an action plan in 2008 followed by a tripartite agreement between the government, the Danish Confederation of Trade Unions, and the Confederation of Danish

Employers. The agreement encompassed 39 initiatives including a national RTW program. The Danish national RTW program is funded with 32 million euros from the Danish National Prevention Fund and 4.3 million euros from the Ministry of Employment and includes 21 of the 98 Danish municipalities. The Danish National Research Centre for the Working Environment (NRCWE) was appointed to develop the Danish RTW program in accordance with the action plan, existing sickness management legislation, and previous experiences from national and international intervention studies (9, 13).

To date, most RTW interventions have been developed for a very specific target group (eg, employees with musculoskeletal problems) (10, 14). However, interventions encompassing a broad target group are more feasible to implement in practice. Moreover, there is a need for RTW interventions that can reach workers without fulltime employment (ie, temporary agency workers and the unemployed) because these groups are particularly prone to labor market exclusion (15). The Danish RTW program is, to our knowledge, currently the largest RTW program in the world. The ambitious goal of this program is to encompass a broad group of sick-listed persons with almost no restrictions regarding reason for sickness absence or employment status (employed, self-employed, unemployed). To accommodate the needs of such a diverse target group, a "one-size fits all" intervention was considered inappropriate. Rather, a complex organizational program was developed. The program aims to improve the municipal sickness benefit management by introducing multidisciplinary RTW teams, standardized procedures for workability assessments, and a comprehensive training course for all members of the RTW teams. Analyzing and understanding the effects of such a complex program requires a comprehensive evaluation, involving both an effect and process evaluation. The purpose of this article is to describe the content and aims of the program as well as the design and the methods of the evaluation.

Methods

In the following, we first describe *care as usual*, which comprises the ordinary sickness benefit management procedures in Denmark. Next we present the content of the Danish RTW program. Finally, we present the aims, design, and methods of the evaluation of the RTW program. The effect evaluation is based on a parallel and a stratified cluster-controlled design. Accordingly, the allocation of participants to the RTW program versus ordinary sickness benefit management takes place both at the municipal and individual beneficiary level. These two designs are described separately.

Ordinary sickness benefit management in Denmark

In Denmark, municipal sickness benefit offices are responsible for payment of sickness benefits – except for the first three weeks which are paid by the employer. All employed, self-employed, and unemployed persons in Denmark are eligible for sickness benefits for a general maximum of 52 weeks. Extensions can be granted for a further 52 weeks – thereafter the person might receive other kinds of social transfer payments if not back at work.

The municipal sickness benefit offices have the formal right to decide if a person is entitled to sickness benefits. The officers may require medical certificates, but this is not mandatory. Thus, often the officers rely on the information from the beneficiary, for instance regarding their diagnosis. According to the Danish sickness benefit legislation, the municipal sickness benefit offices have to assess and classify all sick-listed persons into three categories. This categorization is conducted by designated municipal assessment officers. Category 1 includes beneficiaries who are likely to return to work within three months. Category 2 includes beneficiaries who are not likely to return to work within three months, but who are currently able to participate in RTW activities or gradually return to work. Category 3 includes beneficiaries who are not likely to return to work within three months and are not able to participate in any RTW activities. This categorization is usually based on information from a brief questionnaire filled out by all beneficiaries. The main aim of the categorization is to prioritize time and efforts for beneficiaries at high risk for prolonged absence from work.

In Denmark, employers have very little responsibility for sickness absence management, whereas municipal officers have been appointed the role as case managers. Regular follow-up consultations with the beneficiaries are a central part of the sickness benefit management to revise the initial categorization and ensure that the beneficiary is still eligible for sickness benefits.

The first consultation must take place before the end of the eighth week of absence either face-to-face or by telephone (16). The frequency of the next follow-up consultations depends on the initial assessment of the sick-listed beneficiary and the subsequent categorization. More specifically, municipal officers are obliged to follow-up on beneficiaries in category 2 every fourth week and every eighth week for beneficiaries in category 1 and 3.

At the end of the first consultation, the municipal officers must develop a plan, which includes RTW activities and goals. RTW activities can include RTW counseling, stress- and pain-management, workability training, gradual RTW, and/or work modifications. However, the sickness benefit law does not specify which kind of activities should be available. Initiation of RTW

activities therefore depends on the assessment of the individual officer and on resources in the municipalities, which might vary considerably.

The sickness benefit law strongly urges the municipal officers to coordinate the RTW activities with other relevant stakeholders, such as employers and health professionals. However, coordination may be limited in practice. One study indicated that municipalities contact the employer in about 10%, and the general practitioner in about 9% of all sickness benefit cases (16). The study included category 1 beneficiaries, for whom contacting employers and general practitioners might not be necessary. Hence, contact with employers and general practitioners may be more frequent for category 2 and 3 beneficiaries who are at high risk for prolonged absence. Since 2007, sickness benefit legislation has been changed, requiring municipal officers to contact employers. However, so far it has not been evaluated if this has improved coordination and cooperation among stakeholders.

Aims and content of the return-to-work program

The Danish RTW program is conducted in 21 municipalities covering all regions of Denmark. The overall goal of the RTW program is to reduce sickness absence and improve RTW, health, and workability. The development of the program was guided by two recently published white papers summarizing current knowledge on RTW with regard to musculoskeletal (17) and mental health problems (18) and by a design advisory committee consisting of national and international experts on RTW research and interventions. Based on these recommendations, a multidisciplinary, coordinated, and tailored RTW program was developed. The program consists of three core elements that aim to change the organization and procedures of sickness absence management. The core elements are: (i) establishment of multidisciplinary RTW teams within the municipalities, (ii) introduction of standardized workability assessments and multidisciplinary sickness absence management procedures, and (iii) a comprehensive training course for all multidisciplinary RTW teams prior to the program. Basically, the program builds on the notion that these three elements will improve the municipal sickness absence management, which will increase the RTW, health, and workability of the sick-listed beneficiaries. More specifically, we hypothesize that the three elements promote a faster and more interdisciplinary workability assessment process, improve coordination between RTW teams and external stakeholders (ie, workplaces, general practitioners), and ensure a faster initiation of RTW activities that are better tailored to the needs of the sick-listed beneficiary. Figure 1 shows the core elements of the program and the expected pathways to RTW, workability, and health.

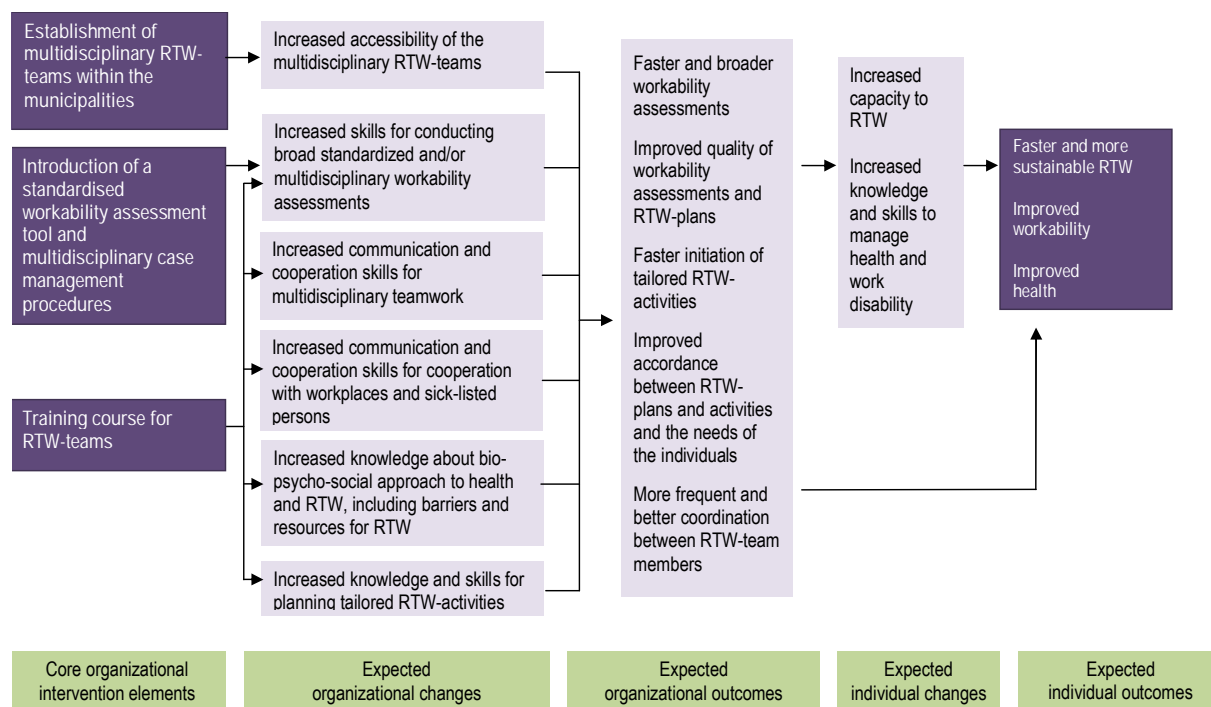


Figure 1. Core program elements and expected pathways to return to work (RTW), workability, and health.

Establishment of multidisciplinary teams. Depending on their population size, the municipalities in the program must establish an appropriate number of multidisciplinary RTW teams. Each team consists of two RTW coordinators (municipal sickness benefit officers), a psychologist, a physical therapist, a psychiatrist, and a physician (specialist in occupational, social, or general medicine). The NRCWE regulates the intake of beneficiaries through the randomization procedures ensuring an annual intake of 170 beneficiaries per RTW team. Therefore the RTW teams have an upper limit to their caseload, which is not the case in ordinary sickness absence management. The RTW coordinator is responsible for conducting regular follow-up of all sick-listed participants in accordance with the law (at least every fourth week for beneficiaries in category 2) and coordinate RTW initiatives with the other members of the multidisciplinary RTW team. All members of the RTW teams are obliged to conduct weekly multidisciplinary team meetings to discuss the more complex cases. The introduction of the multidisciplinary RTW teams enables closer cooperation between municipal officers and health professionals compared to ordinary sickness benefit management.

Introduction of a standardized assessment tool and multidisciplinary sickness absence management procedures. We developed a standardized RTW assessment tool based on a biopsychosocial understanding of health and

disability. The RTW assessment tool should enable the RTW coordinators to conduct a systematic assessment that helps to identify the needs of each sick-listed beneficiary. The assessment tool covers barriers and resources for RTW related to physical and mental health, work, and occupational experiences. The tool must be used in the first consultation between the RTW coordinator and the sick-listed beneficiary; the assessment takes about one hour. The extensive RTW assessment tool secures a comprehensive assessment of the sick-listed beneficiary's situation in the beginning of the RTW process and thus functions as an important basis for further activities. Using this tool, we expect that RTW coordinators can manage about half of all cases without discussing the case at the weekly multidisciplinary team meetings. Nevertheless, the RTW coordinators can always contact the other members of the RTW team to clarify health-related questions. In more complex cases, the RTW coordinators can refer beneficiaries to other team members for further workability assessment, after which these cases are discussed with all RTW team members in the mandatory multidisciplinary team meetings to qualify assessments and decisions. The possibility of direct and frequent exchange between all members of the multidisciplinary team is one of the key aspects in which the RTW program substantially differs from ordinary sickness benefit management. While ordinary sickness benefit officers can request further

information from other health professionals, they do not have the possibility to discuss a complex case with several experts at the same time. Additionally, requesting assessments from one or several experts takes time and the experts' assessments do not take each others viewpoints into account. The weekly multidisciplinary team meetings, however, create a multidisciplinary forum, which enables the team to consider all relevant aspects at the same time and together develop the most appropriate RTW plan.

Just as in ordinary sickness benefit management, and in accordance with the law, the RTW coordinators are responsible for developing an individual RTW plan and conducting the obligatory consultations with all beneficiaries. Additionally, in the Danish RTW program, the RTW coordinators are also responsible for coordinating the different RTW activities with a special emphasis on close collaboration between the RTW team members and external stakeholders, for instance the employer. The RTW activities can – as with ordinary sickness absence management – include meetings with workplaces, work modifications, workability training, gradual RTW, education/training (eg, psycho-education, ergonomics training, physical exercises, and stress and pain management). In the Danish RTW program, the health professionals in the RTW team can participate in the RTW activities ie, meetings with workplaces or education/training. We hypothesize that having the same health professionals participating in both the assessment and the follow-up activities will improve coordination and continuity compared to ordinary sickness benefit management. To further support a more standardized sickness management procedure and good information flow between all RTW team members, several other tools have been developed for the program. These include guides for the meetings between the sick-listed beneficiary and the other RTW team members (psychologists, physiotherapists, physicians, and psychiatrists) and a number of templates for information exchange between RTW team members.

Training course for RTW team members. Before the onset of the RTW program, all RTW coordinators, psychologists and physiotherapists participate in a 3-week training course, whereas physicians and psychiatrists participate in selected parts of the course. The course consists of a mixture of theoretical lectures, practical casework, role plays, and exercises. The aim of the course is to ensure that all RTW teams have the necessary knowledge and skills to deliver the program. Therefore, the course focuses on topics such as a biopsychosocial understanding of health, the central role of the RTW coordinator (eg, coordinating the input from the other team members and advancing the RTW process) and the multidisciplinary teamwork (eg, using and respecting

each others' expert knowledge and contributing to a joint RTW plan). Other topics are the cooperation with workplaces and other stakeholders (eg, the beneficiaries' physician) and the RTW team members' competencies for working with beneficiaries (ie, enhancing the beneficiaries' resources and capacity for RTW and initiating tailored RTW activities) (see figure 2 for an overview of the main topics of the RTW training course). Following the training course, two course managers from the research group at the NRCWE visit all RTW teams throughout the program period to facilitate the implementation process.

Aims and design of the evaluation

The evaluation of the program consists of both an effect and process evaluation, which were designed – and are currently being conducted – by a research group at the

- The biopsychosocial understanding of health and illness
- How to use cognitive methods in working with sick-listed beneficiaries
- Special focus (for RTW coordinators) on beneficiaries with mental health problems
 - » Introduction to common mental health problems
 - » How to conduct a RTW-assessment with beneficiaries with mental health problems
 - » RTW-activities for beneficiaries with mental health problems
- Developing RTW-group activities (for psychologists and physiotherapists) with focus on:
 - » Pain management (cognitive methods)
 - » Stress-management (psychological and physiological) (cognitive methods)
 - » Psycho-education
- How to work in a multidisciplinary team
 - » Understanding the meaning of multidisciplinary team work
 - » Using and respecting each others competencies while working towards the same goal
- Case management in the RTW-program
 - » Working with the RTW-assessment tool
 - » Deciding when to approach the other team members for further assessment
 - » Organizing and conducting the weekly multidisciplinary RTW-team meetings
 - » Organizing the information flow between all RTW-team members, the beneficiaries and external actors
- Contact and cooperation with workplaces
 - » Cooperation with work place consultants
- Contact and cooperation with the external actors
 - » Information exchange and cooperation with the beneficiaries' physician
 - » Health care in general (hospitals etc.)
 - » Unemployment office
- Brush up on sickness benefit law on cooperation with workplaces (for RTW coordinators)
- Basic education on sickness benefit law for health professionals (psychologists, physiotherapists, physicians, psychiatrists)

Figure 2. Main topics of the return-to-work (RTW) training course.

NRCWE. The research group is assisted by an external independent expert evaluation advisory committee, consisting of leading Danish and international RTW researchers. The evaluation advisory committee was established to improve the quality of the evaluation, given that both development and evaluation of the Danish RTW program is conducted by the same organization (NRCWE). Consequently, the advisory committee critically reviews evaluation plans, data analyses, and interpretation in accordance with the state of the art in RTW research.

We use the CONSORT statement (19) and the extension for cluster randomized trials (20) to describe the design of the effect evaluation, which is conducted in two studies: a parallel group randomized trial (randomized at the individual level of the study participants within municipalities) and a stratified cluster-controlled trial (cluster-controlled on the level of the municipalities). The effect evaluation tests the following hypotheses: Participants in the intervention (i) have a shorter duration of full-time sickness absence, (ii) have a longer time until recurrent long-term sickness absence (have a more sustainable RTW), (iii) are faster in achieving a full RTW and (iv) report a more positive development in self-rated general, mental, and physical health, workability, pain, and sleep. Further, we hypothesize (v) that the RTW program is cost-effective (this hypothesis will be tested by the Danish Institute of Governmental Research that conducts the economic evaluation).

The process evaluation serves both a formative and a summative purpose (21). The formative purpose involves a continuous use of process data for optimizing the program through learning (ie, through identifying creative solutions to implementation challenges) and “keeping the program on track” (21). In general, the aim of the summative purpose is to determine: (i) whether the expected target population is reached, (ii) how the program is implemented and whether it is implemented as intended, (iii) how the beneficiaries, the RTW teams, and other key stakeholders perceive the program, and (iv) whether (and how) contextual factors influenced the implementation.

Recruitment of municipalities

In 2009, the Danish National Prevention Fund invited all 98 Danish municipalities to apply for participation in the program. The applications had to include a plan for the implementation of the program. A total of 44 municipalities applied for participation. In close cooperation with the Danish National Prevention Fund, we selected a total of 34 eligible municipalities based on quality (eg, accordance between implementation plans and the program concept) and feasibility of implementation plans (eg, with respect to availability of resources). We excluded

municipalities that already had smaller RTW projects that might have affected program implementation. The two largest municipalities in Denmark, Copenhagen and Aarhus, were *a priori* selected for inclusion in the project due to the possibilities of strong study designs (randomization of individuals and cluster allocation of sickness benefit sub-offices within the municipality, respectively). We grouped the remaining 32 eligible municipalities in distinct strata based on size and implementation plan. Within each stratum, we first randomly assigned an equal number of applicants to the RTW program (the intervention group) and ordinary sickness benefit management (the control group). To allow as many applicants as possible to implement the program for the whole program period, we then randomly assigned applicants to the intervention group until we reached the limit of the budget. Thus, the final sample consisted of 21 municipalities, of which 13 were randomly assigned to the RTW program (intervention) and 8 to ordinary sickness absence management (controls) (figure 3). Although we used randomization to allocate municipalities into the intervention and control groups, we opted to name this part of the study a “stratified cluster-controlled trial” since the number of randomization units are probably too small to achieve perfectly comparable groups. The program was launched 1 April 2010 in all municipalities assigned to the intervention group and will end 31 March 2012. To increase the control municipalities’ incentive for participating in the RTW program, these municipalities were offered the full program after one year (1 April 2011–31 March 2012).

Study population

We aim to recruit approximately 19 500 working-age beneficiaries on long-term sickness absence (≥ 4 weeks) from the 21 municipalities. We include beneficiaries who are evaluated as able to participate in RTW programs and gradually return to work (category 2), regardless of their employment status (employed, self-employed, unemployed) and reason for sickness absence. We exclude beneficiaries in category 1 because they are expected to be able to return to work within 3 months on their own and beneficiaries in category 3 because they, by definition, are not able to participate in RTW programs. Finally, we exclude women who are sick-listed due to pregnancy-related health problems.

The parallel randomized controlled trial

The parallel RCT design with individual randomization is usually the preferred design for effect evaluations. In this study, only three municipalities (Copenhagen, Silkeborg, and Esbjerg) are eligible for the parallel RCT because they meet the following criteria: (i) they have

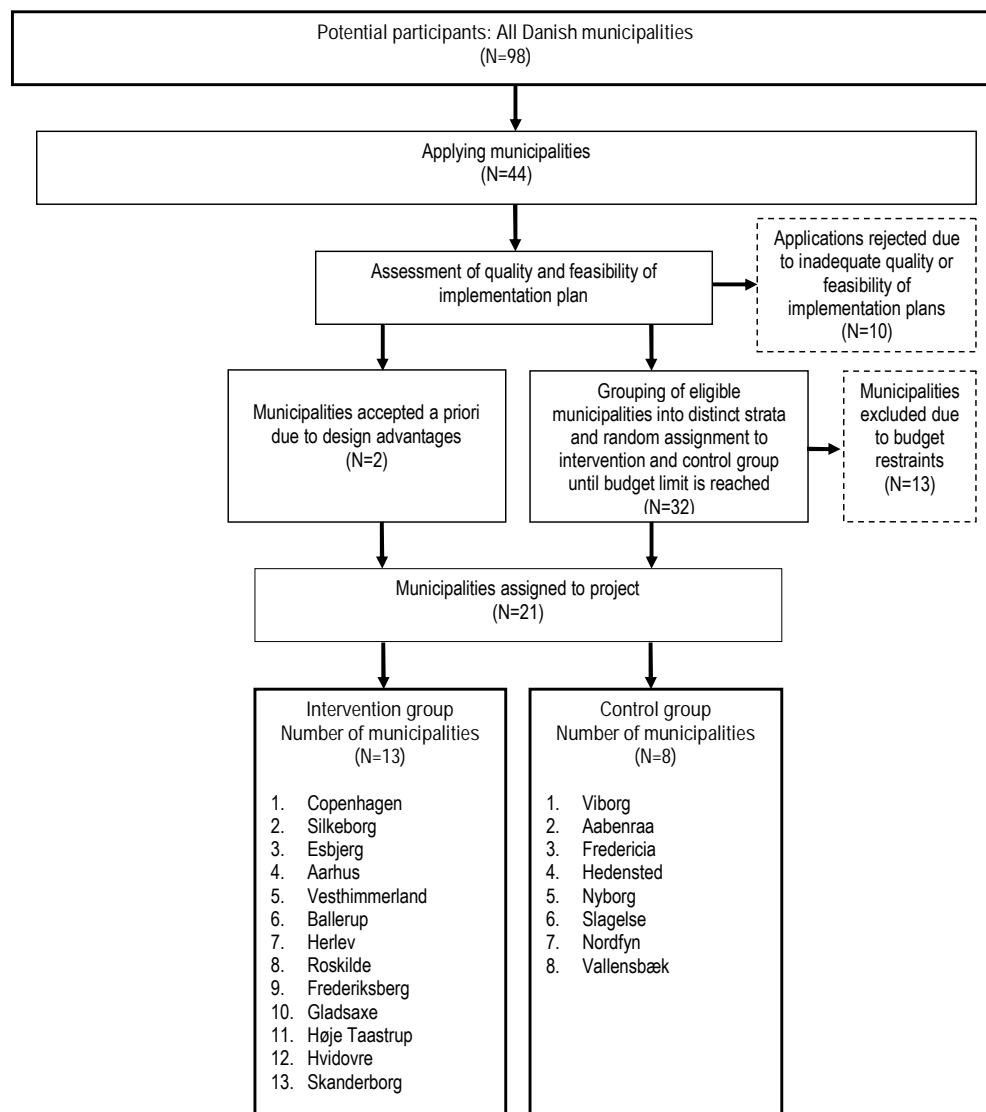


Figure 3. Recruitment of municipalities

separated sub-units of their sickness benefit office serving the same population allowing for randomization of sick-listed beneficiaries to an intervention or a control office; and (ii) the sickness benefit sub-units are geographically separated, thereby reducing the risk of contamination between RTW coordinators and ordinary sickness benefit officers. In the three municipalities included in the RCT, a designated municipal assessment officer or an administrative employee administers the randomization using a web-survey program, which automatically allocates all eligible beneficiaries to a control or an intervention sickness benefit unit. The result of the randomization is instantly available for the sickness benefit officer and registered in a central database at NRWCE. The RCT runs from April 2010–March 2012 and is expected to include

approximately 6600 beneficiaries of which approximately 3600 beneficiaries will receive the intervention and approximately 3000 will receive ordinary sickness absence management (controls).

The stratified cluster-controlled trial

The stratified cluster-controlled trial encompasses all 21 municipalities. In total, the cluster-controlled trial runs for two years and is expected to include approximately 19 500 beneficiaries, of which approximately 12 600 will receive the intervention and approximately 6900 will receive ordinary sickness absence management (controls). Table 1 gives an overview of the municipalities and their status as either control or intervention

municipalities during the first and second year of the program. The municipalities with both intervention and control groups (Copenhagen, Silkeborg, Esbjerg, and Aarhus) contribute with sick-listed beneficiaries in the control and intervention group during both years. The nine municipalities assigned to the intervention group (Vesthimmerland, Ballerup, Herlev, Roskilde, Frederiksberg, Gladsaxe, Høje Taastrup, Hvidovre, Skanderborg) contribute with beneficiaries in the intervention group throughout both years. In contrast, the eight municipalities assigned to the control group (Viborg, Aabenra, Frederica, Hedensted, Nyborg, Slagelse, Vallensbæk, Nordfyn) continue with ordinary sickness absence management during the first year but are offered the full program in the second year. Consequently these municipalities contribute with sick-listed beneficiaries to the control group only during the first year and with beneficiaries to the intervention group in the second year.

Main and secondary outcomes

Duration of sickness absence is measured in days from first day of sickness absence until last day on full-time sickness absence. Consequently, beneficiaries on part-time sick leave or other types of social transfer payments are not categorized as sick-listed. Recurrence of sickness absence is measured in days from first day of full RTW until recurrent long-term sickness absence (sickness

absence >3 weeks). Finally time to RTW is measured in days from first day of absence until full RTW (no longer receiving any social transfer payments, ie, being self-supporting) for all beneficiaries sick-listed from employment. The secondary outcomes (changes in self-rated general, mental and physical health, workability, pain and sleep) are measured by questionnaires.

Data for effect evaluation

Data registered at the sickness benefit office. From the registration of all sickness absence cases (categories 1, 2, & 3) conducted by the sickness benefit offices, a range of demographic and health-related baseline data is available. The data is retrieved from the administrative form used by sick-listed beneficiaries to apply for sickness benefits. From the form, we retrieve information on gender, age, level of education, employment status (employed, unemployed, self-employed), reason for sickness absence, and date of first day of absence. In addition, the sickness benefit offices register the sickness absence category in a central database. Additionally, but only for sick-listed beneficiaries in category 2, the result of the randomization is registered (table 2).

Questionnaires. A self-administered questionnaire is distributed to all participants (intervention and control) at baseline. The questionnaire includes sociodemographic measures (eg, occupational group, employment status and education); health-related behavior before becoming sickness absent (smoking, alcohol consumption, diet, and exercise); height; weight; recent use of the healthcare system; general, physical and mental health; sleep; pain perceptions and fear avoidance; general self-efficacy; workability; and prior sickness absence (during the last 12 months). Finally, we also ask the respondents about their overall job satisfaction, how their workplace managed their sickness absence, and which factors contributed to their decision to report sick. Six months after the baseline questionnaire, we send a follow-up questionnaire to all who responded to the first questionnaire. This questionnaire repeats the questions on self-rated health, workability general self-efficacy, employment status, and current health-related behavior. Additionally, it includes questions about the respondent's assessment of the RTW process (eg, the municipal management of their sickness absence). After 12 months, the baseline respondents receive a final follow-up questionnaire that again includes questions on self-rated health, workability, employment status, and current health-related behavior (table 2).

Table 1. Intervention (INTV) and control (CONT) municipalities in the first and second year of the program.

Municipalities	Year 1	Year 2
	April 2010–March 2011	April 2011–March 2012
Copenhagen ¹	INTV + CONT	INTV + CONT
Silkeborg ¹	INTV + CONT	INTV + CONT
Esbjerg ¹	INTV + CONT	INTV + CONT
Aarhus ²	INTV + CONT	INTV + CONT
Vesthimmerland	INTV	INTV
Ballerup	INTV	INTV
Herlev	INTV	INTV
Roskilde	INTV	INTV
Frederiksberg	INTV	INTV
Gladsaxe	INTV	INTV
Høje Taastrup	INTV	INTV
Hvidovre	INTV	INTV
Skanderborg	INTV	INTV
Viborg	CONT	INTV
Aabenra	CONT	INTV
Frederica	CONT	INTV
Hedensted	CONT	INTV
Nyborg	CONT	INTV
Slagelse	CONT	INTV
Vallensbæk	CONT	INTV
Nordfyn	CONT	INTV

¹ These municipalities are selected for the parallel randomized controlled trial (RCT).

² Aarhus also has multiple sub-offices but is not part of the RCT because the sickness benefit offices serve geographically distinct areas.

Data from national registries

We obtain data on sickness absence and RTW from the Danish Register of Sickness Benefit Compensation

Table 2. Data to be collected for the evaluation of the Danish return-to-work (RTW) program. [SBO=data from sickness benefit offices; NR=data from national registries; Q=data from self-administered questionnaires; Baseline=at baseline, 6=at 6 months follow-up, 12=at 12 months follow-up; Continuously=data collected continuously over the follow-up period]

Variable	Data source	Time of data collection	Origin of items or scales in the self-administered questionnaires (Reference)
Randomization, sickness benefit category			
Randomization status	SBO	Baseline	---
Sickness benefit category	SBO	Baseline	---
Sociodemographic characteristics			
Age	NR/SBO	Baseline	---
Gender	NR/SBO	Baseline	---
Education	NR/SBO/Q	Baseline	Adjusted items from the Danish Work Environment Cohort Study (26)
Occupational sector	NR/Q	Baseline	Adjusted items from the Danish Work Environment Cohort Study (26)
Socioeconomic status	NR	Baseline	---
Marital status	NR	Baseline	---
Country of origin	NR	Baseline	---
Health, behaviors, attitudes			
Health behaviors, height and weight	Q	Baseline/6/12	Adjusted items from the Danish Health and Morbidity Survey 2005 (27)
Recent use of healthcare system	Q	Baseline	Adjusted items from the Danish Health and Morbidity Survey 2005 (27)
Diseases diagnosed by a physician	Q	Baseline	Adjusted items from the Danish Work Environment Cohort Study (26)
General health	Q	Baseline/6/12	Single Form 12-items (SF-12) (28)
Physical health	Q	Baseline/6/12	SF-12 (28)
Mental health I	Q	Baseline/6/12	SF-12 (28)
Mental health II	Q	Baseline/6/12	Subscale SCL8-AD (29)
Sleep patterns	Q	Baseline/6/12	Karolinska Sleep Questionnaire (30, 31)
Pain perceptions and fear avoidance	Q	Baseline/6/12	Linton et al (32)
Workability	Q	Baseline/6/12	Single items from the Work Ability Index (33)
General self-efficacy	Q	Baseline/6/12	Schwarzer et al (34, 35)
Workplaces factors			
Job satisfaction	Q	Baseline	Copenhagen Psychosocial Questionnaire (COPSOQ) (36)
Self attributed causes for sickness absence	Q	Baseline	Items developed for this study
Employers', colleagues', own attitudes to RTW	Q	Baseline	Items developed for this study
Employment, sickness absence and RTW			
Reasons for sickness absence	SBO	Baseline	---
Date of first day of absence	SBO	Baseline	---
Employment status	Q/SBO	Baseline/6/12	Items developed for this study
Perception of RTW process	Q	6	Items developed for this study
Employer dealing with sickness absence	Q	Baseline	Items developed for this study
Sickness absence during the last 12 months	Q	Baseline	Items developed for this study
Sickness absence/RTW	NR	Continuously	---

Benefits and Social Transfer Payments (RSS 1.0), which contains information on all social transfer payments, including sickness benefits, on a daily basis. Data on age, gender, education, socioeconomic status, occupational sector, country of origin, and marital status is obtained from Statistics Denmark (table 2)

Statistical analysis

We retrieve primary outcome data on all study participants from national registries and employ Cox proportional hazard models to analyze the effects on sickness absence and RTW status. The statistical analyses are based on the intention-to-treat approach. First day of sickness absence is used as origin for the time scale. Data are left-truncated at date of first consultation because no effect of intervention can be assessed until

it is determined whether the beneficiary will receive the intervention or not. We right-censor beneficiaries, who become old-age pensioners, die, emigrate, or leave the labor market due to maternity/paternity. The analyses based on the parallel RCT will be adjusted for municipality, whereas the stratified cluster-controlled trial will be adjusted for potential confounders, eg, sociodemographic characteristics. Effects on changes in secondary outcomes (health, workability, pain, and sleep) from the 3-waved questionnaire are analyzed using generalized linear mixed models and adjusted for possible confounders. Finally, for both primary and secondary outcomes, we will perform subgroup analyses looking at effects for different sub samples of the participants, for instance with regard to employment status at baseline (employed, self-employed, and unemployed), different reasons for absence (mental health problems, musculoskeletal prob-

lems, and other reasons), education (high, medium, and low), gender and age, and country of origin (Denmark, other western countries, and non-western countries).

Power calculations

The power calculations were based on the assumptions that there is a constant RTW rate and an average RTW time of 20 weeks after entering the program. Explorative analyses of register data covering the Danish population showed that these assumptions approximately were fulfilled for sickness absence lasting >6 weeks. Also from register data, a standard deviation of on average 1.3 weeks between municipalities was estimated. By simulations in which municipalities were included as a random effect (frailty term), it was found that in the parallel RCT with a study population of 6600 beneficiaries, of which approximately 55% are receiving the intervention, there is a power of 80% to detect a 7.5% (1.5 week) reduction in average duration of sickness absence. A similar analysis based on the cluster-controlled trial covering 19 500 beneficiaries, of which 65% are receiving the intervention showed, that this trial has a power of 80% to detect a 5.5% (5.5 working days) reduction in average sickness absence duration.

Economic evaluation

The aim of the economic evaluation is to determine whether the RTW program is cost-effective compared to ordinary sickness benefit management. The economic evaluation also includes a cost-benefit analysis from a societal perspective. The costs and benefits of the Danish RTW program are evaluated from the municipal, the public sector, and the societal perspectives. From all three perspectives, costs are the extra municipal costs of the RTW program. These costs consist of municipal set-up costs (eg, buying new equipment) and operating costs (eg, salaries). Benefits, however, differ depending on the perspective. From a municipal perspective, benefits are the reduction in expenditure on social transfer payments (ie, related to sickness absence, unemployment, and permanent disability). This is also the case for the public sector perspective, but these analyses also include the state's share of these transfer payments and the possible reduction in public health expenditure, which we measure based on expenditures on drug prescriptions and doctor visits. Benefits from a societal perspective are the estimated increase in production (measured by earnings) plus possible reduction in (private and public) expenditure on prescription drugs and doctor visits. Data on municipal costs of implementing and running the RTW program relative to the costs of "ordinary sickness absence management" are collected from questionnaires distributed to the head of the sickness benefit office in

each of the participating municipalities. Data on sickness benefits, other transfer payments, doctor visits, and purchase of prescription drugs are obtained from administrative register data.

Process evaluation

The process evaluation follows the framework introduced by Saunders et al (21) which is based on work by Steckler & Linnan (22) and Baranowsky & Stables (23). The framework includes the following seven elements: (i) fidelity (quality), (ii) dose-delivered (completeness), (iii) dose-received (exposure) (iv) dose-received (satisfaction), (v) reach (participation rate), (vi) recruitment, and (vii) context. We summarized the seven elements into four main research questions for the process evaluation: (i) was the expected target population reached? (reach, recruitment), (ii) is the program implemented as intended? (fidelity, dose-delivered, dose-received: exposure), (iii) how did the beneficiaries, the RTW teams, and the external stakeholders experience the program? (dose-received: satisfaction), and (iv) was the implementation influenced by contextual factors? (context). By documenting all these aspects of the implementation process, we will be able to assess to the extent to which the implementation of the program was successful. A successful implementation is a prerequisite for testing the program, as intermediate outcomes and final effects cannot be expected if the implementation failed (24). In the case of a successful implementation, we will investigate if the underlying assumptions of the program (as shown in figure 1) can be confirmed, that is, if the organizational intervention of the program led to the expected organizational and individual changes and intermediate outcomes. This procedure will enable us to distinguish between a potential failure of the implementation and potential failures in the assumptions underlying the program (24).

To conduct this extensive process evaluation we will utilize four data sources: questionnaires, focus group interviews, individual interviews, and municipal data and documents. The information from these data sources will be used to assess the implementation according to the above-mentioned framework (21). In a second step, we will use the same information to investigate if the program led to the expected changes and intermediate outcomes. Table 3 illustrates how the different data sources are used to evaluate the implementation of the program elements and the expected changes.

In addition to these data sources, we will retrieve relevant information from registries (also used for effect evaluation, see description under "Data from national registries") to assess recruitment and reach (participation rate).

In the following, the main data sources for the process evaluation are explained more in-depth. The meth-

Table 3. Process evaluation data sources to evaluate the implementation and expected changes. [RTW=return to work.]

	Implementation of core organizational program elements	Expected organizational changes	Expected organizational outcomes	Expected individual changes
Questionnaires to RTW team members	X	X	X	
Focus groups and individual interviews with RTW team members	X	X	X	X
Individual interviews with municipal managers	X	X	X	
Questionnaires to sick-listed beneficiaries			X	X
Individual interviews with sick-listed beneficiaries			X	X
Individual interviews with employers/workplaces			X	
Municipal data and documents	X		X	

ods for the process evaluation are developed continuously during the program period to enable us to focus on unforeseen implementation challenges. Thus, the final process evaluation may divert somewhat from the present evaluation plan (eg, with regards to the total number of interviews) or methods used.

Questionnaires for RTW team members. We distribute a six-waved questionnaire to all RTW team members to assess if the RTW teams utilize the different program tools and procedures, to what degree the RTW teams were satisfied with the training course, and whether the implementation is influenced by internal or external contextual factors. The baseline questionnaire is distributed to all RTW teams prior to the start of the program and includes questions about the respondents' education, occupational experience, and expectations about and motivation for participating in the program. The follow-up questionnaires are distributed throughout the program period and include questions about the standardized RTW assessment tool, management support for implementing the program, cooperation within the RTW team and cooperation with the sick-listed beneficiaries and their workplaces etc.

Individual interviews and focus groups with RTW team members. Focus group interviews with the RTW teams (about 10), individual interviews (about 20) with selected RTW team members, and group interviews (about 50) with the different professions represented in the RTW teams (RTW coordinators, psychologists etc) are conducted as a supplement to the questionnaires. This enables a more detailed understanding of the multidisciplinary team work, the use of the RTW assessment tool and other standardized procedures, and cooperation with the workplaces of the sick-listed beneficiaries.

Questionnaire for the managers of sickness benefit offices. We conduct a questionnaire survey among managers from all municipal sickness benefit offices at the end of the program. The municipal managers are responsible for the facilities and working conditions of the RTW teams as well as for providing support and resolving organizational problems that might influence the program. In addition, they have a unique insight into implementation problems, which may arise along the way. Thus, the survey among these managers contributes to our understanding of how the program is implemented and how internal and/or external contextual changes might influence the implementation.

Individual interviews of employers of sick-listed beneficiaries. We conduct interviews with employers or the closest supervisors of sick-listed beneficiaries (about 10) to assess how they experience the RTW program. Employers are one of the most important stakeholders in the RTW process. The interviews investigate, whether the employers feel sufficiently involved in the RTW process of their employees, eg, whether they are informed about the employees' RTW plan and how they experience the cooperation with RTW team members.

Individual interviews of sick-listed beneficiaries. A series of individual interviews with beneficiaries (about 50) participating in the program is conducted to investigate their experiences. The interviews address, whether the beneficiaries are informed about and included in decisions about their RTW activities, how they experience the communication with the RTW team members and their overall satisfaction with the program. To achieve maximum variation in RTW experiences, we select a heterogeneous group of sick-listed beneficiaries regarding reason for sickness absence, employment status at baseline, residential municipality, and country of origin.

Questionnaire for the sick-listed beneficiaries. The six months follow-up questionnaire (part of the 3-waved questionnaire to all sick-listed beneficiaries in the inter-

vention and control groups of the program) includes questions about the overall satisfaction with sickness benefit management, cooperation between the municipal officers and external stakeholders (including the workplace), delays in sickness management, involvement of the sick-listed beneficiary in decision-making, and satisfaction with educational RTW activities. Furthermore – but only for beneficiaries in the intervention group – the questionnaire includes questions about the contribution of the RTW team members to the RTW process.

Documents and databases. To describe how RTW activities are used, we obtain data from the municipal administrative systems of the intervention municipalities (including data on control group beneficiaries in the RCT municipalities). This includes data from approximately 5500 beneficiaries, who were enrolled into the program during the period June 2010–May 2011. We obtain data on the frequency of contact with employers and other external stakeholders and referrals to RTW activities. Among other things we will compare efforts in ordinary sickness absence management and the RTW program. Additionally, for program participants, we also obtain information on referrals to RTW team members.

Discussion

In a recent systematic review of the effectiveness of RTW interventions for persons on sickness absence due to musculoskeletal problems (25), the authors concluded that most interventions appear beneficial but effects are rather small and publication bias may have occurred. In addition, intervention studies were typically small and of limited quality. To our knowledge, the Danish RTW program is, to date, the largest RTW intervention ever conducted. The program combines a multidisciplinary, coordinated, and tailored approach delivered by specially trained RTW coordinators and multidisciplinary RTW teams within the municipal sickness benefit offices. The evaluation of the program is extensive and includes effect, process, and economic evaluations. The Danish RTW program therefore has the potential to provide evidence-based knowledge on effects and cost-effectiveness as well as useful insights into the feasibility and barriers of implementing a multidisciplinary, coordinated, and tailored RTW program on a large scale.

Strengths and limitations of the study

The study design has several important strengths. As one of the few RTW studies, the program includes beneficiaries regardless of their reasons for sickness absence and employment status. This makes it possible to study

the overall program effects under circumstances, which are similar to every day practice. In addition, the large sample size allows us to conduct a number of subgroup analyses that often cannot be performed due to limited statistical power. More than 20% of the 98 Danish municipalities participate in the program, and the program covers both large cities and rural areas. This increases the possibility of generalizing the results. Moreover, the risk of contamination between the RTW coordinators providing the RTW program and the social insurance officers providing ordinary sickness benefit management is diminished in both trials. In the parallel RCT, sickness benefit sub-offices providing the RTW program and ordinary sickness benefit management are geographically separated within the municipality and chances for knowledge exchange are thereby reduced. In the stratified cluster-controlled trial, ordinary sickness benefit management is conducted in separate municipalities thereby reducing the chances for contamination.

Another strength of the study is that the main outcomes (sickness absence and RTW) are assessed using register data eliminating recall and non-response bias. Furthermore, the implementation of the program is carefully monitored through an extensive process evaluation, which allows us to detect and understand variations in the implementation, eg, between municipalities. The identification of “creative solutions” in some municipalities can be used as inspiration for further program development. In addition, major contextual changes, such as, new laws or socioeconomic changes are documented so that their impact on outcomes can be discussed.

The program also faces a number of challenges. The Danish RTW program is a highly complex organizational intervention, which is incorporated into the structures and working procedures of the municipal sickness benefit offices. Thus, it is necessary to give the municipalities some degree of flexibility to adapt the program to local circumstances. Additionally, the program is tailored to the need of the individual and therefore differs among beneficiaries. Such individually tailored interventions are assumed to be advantageous for the sick-listed beneficiaries but present a challenge for researchers by making evaluation more complex. Finally, the assessment of the secondary outcomes (self-rated health, workability, pain, and sleep) relies on questionnaire data. Non-response tends to be higher for people with more severe health problems, lower education and for immigrants and people with reading difficulties, which might bias the results.

Concluding remarks

If successful, the program, or parts of it, might be integrated into the existing structures of the municipal sickness benefit offices and thereby help to improve RTW

for sick-listed beneficiaries in all of Denmark. Success, however, will not only depend on the effectiveness, but also on the feasibility of the program. Although the potential impact of the study is most relevant within the Danish context, effects of large system changes are also of international relevance. A recent OECD report on sickness, disability and work pointed out that all OECD countries face much of the same problems regarding the management of long-term sickness absence and RTW (2). The report concluded that even though each country uses different schemes and approaches, there might be much to learn from what is done elsewhere (2). The program objective of achieving a faster and more sustainable RTW is of high societal relevance. Human and economic costs could be lowered and labor force supply could be increased. The first results of the study will be available in 2013.

Ethical considerations

The study has been notified to and registered by the Danish Data Protection Agency (<http://www.datatilsynet.dk>). According to the Danish National Committee on Biomedical Research Ethics (written communication) the intervention does not need their approval as it does not include biomedical research.

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