

Study protocol:

Testing the WHO QualityRights training: a new intervention to promote the human rights of persons with psychosocial disabilities

This study protocol was submitted as a PhD dissertation proposal at Columbia University (New York) and discussed on May 6, 2021, by Dr. Maria Francesca Moro.

It is part of a project funded by the European Commission (EIDHR 2018-400431), "Empowering Persons with Psychosocial Disabilities to Fight for Their Rights: Implementing the CRPD and QualityRights Principles in Ghana, Lebanon, and Armenia."

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1. Introduction and specific aims

People with psychosocial disabilities are commonly exposed to human rights violations (e.g., discrimination and exclusion from society, inability to access health services, physical, sexual, and psychological abuse, violence, and neglect, denial of the right to legal capacity) within the mental health care system and in the general community [1-5]. Such violations occur in all countries [2, 4] and are not only a problem from an ethical point of view but additionally have profound repercussions on the health of persons with psychosocial disabilities. The relationship between human rights violations and mental health is complex and bidirectional: psychosocial disabilities make people more vulnerable to human rights violations, and, in a vicious cycle, human rights violations negatively impact mental health.

Although psychiatric facilities are the very institutions responsible for the care and support of people with psychosocial disabilities, they are also often places in which persons with psychosocial disabilities are victims of inhumane treatments, including psychological, physical, and sexual abuse or violence [2, 4, 6, 7]. The prevalence of these violations is high both in high-income and low- and middle-income countries, and thus it cannot be explained simply by a lack of resources [8]. In many mental health facilities, people with psychosocial disabilities continue to be chained to beds or caged for long periods [2, 5, 9-17], verbal abuse by mental health staff are frequent [4, 18-25], and sedation is often implemented for purposes of control [26-32]. Seclusion and restraints are still frequently used [33-37], often as a punishment [38, 39], although they pose severe threats to health and safety [40, 41].

The mental health sequelae of human rights violations, as well as mental health conditions in general, cannot be treated effectively until the human rights violations themselves stop, particularly in mental health services. Public health, because of its role in the investigation of social determinants of health, development of interventions, and implementation of policies, may provide unique tools to address this problem.

Reasons why these human rights violations continue to be perpetrated in the mental health sector.

To stop these human rights violations, we need to reform mental health systems and thus change mental health professionals' practices leading to violations of people with psychosocial disabilities' rights. However, for this to happen, two main barriers need to be addressed.

One barrier is the lack of human rights literacy among health professionals in general, and thus, also among mental health professionals [42, 43]. This is alarming since human rights documents inform the duties of health professionals [44], who thus should be familiar with the human rights framework. Such ignorance is even more disturbing if one considers that health professionals often have the law-sanctioned authority to restrict human rights. This problem is all the more relevant within the mental health care system, where such restrictions are unfortunately not exceptions but the rule. The second barrier is that many mental health professionals hold negative attitudes towards people with psychosocial disabilities [45, 46]. Many providers also oppose the complete implementation of a human rights-based approach in mental health, which would require to set apart entirely substitute-decision making approaches and the use of coercion – on the basis of disability - in mental health, and move towards a “will and preferences” framework [47]. Indeed, providers have been resistant to this change and are vehemently opposing it [48-52].

Potential strategies to remove these barriers: an analysis of the existing interventions and their limitations.

Over time, strategies with the potential to address these two barriers have been developed. Several interventions attempted to educate mental health professionals on human rights (e.g., through lectures from academics and experts in the field, individual case studies, journal clubs), with positive outcomes [43, 53, 54]. Other initiatives targeted mental health professionals' negative attitudes towards people with psychosocial disabilities and were found to be effective [55]. Educational trainings delivered by an expert (usually a mental health professional) were the most common type of intervention implemented. Other interventions used internet courses, video presentations, module booklets, or contact-based education projects to address providers' stigma towards people with psychosocial disabilities [55]. Overall, these initiatives were found to be somewhat effective in reducing providers' negative attitudes towards people with psychosocial disabilities.

Unfortunately, all these initiatives present important limitations. One problem is that they often do not follow a modern human rights framework, as the one promoted by the United Nations Convention on the Rights of

Persons with Disabilities (UN CRPD). The existing interventions were mainly developed by health practitioners and often reflect their position, even when this is in contradiction with the perspective of people with psychosocial disabilities and their organizations. None of the programs to address providers' stigma focuses specifically on changing attitudes towards people with psychosocial disabilities' role as rights-holders, although this aspect is fundamental for their full participation in society. Additionally, the studies evaluating the impact of human rights training on providers' knowledge about human rights only focused on this aspect and rarely assessed the training's ability to change also providers' attitudes. However, we assume that improvements in attitudes are an important mediator in the relationship between human rights knowledge and a change in practices, our ultimate goal, and thus they should be more carefully assessed. Even among the studies to address health professionals' stigma, only two [56, 57] assessed a change in practices.

Furthermore, all the studies evaluating the efficacy of these different interventions present critical methodological limitations. Many were pre-post intervention studies without a control group. Even when the control group was present, most of the studies were non-randomized, and thus we cannot exclude non-comparability between the intervention and the control group. In the rare cases where a randomized controlled trial was carried out, the samples enrolled were too small to draw definitive conclusions, and no power calculations were provided. Response rates in many pre-post intervention studies were low, particularly in the post-intervention assessments, and this may have caused selection biases. Information bias was an issue in many studies since the changes in knowledge and in attitudes were often evaluated with questionnaires not tested for reliability and validity. No attempt to quantify the impact of these biases was made in any of these studies. Furthermore, although the number of publications on interventions to promote people with psychosocial disabilities' rights (in the mental health sector and more broadly) is growing, no recent attempt has been made to systematically review the literature on this topic to inform future research and interventions.

Justifying a cluster randomized controlled trial (cRCT) to test a new intervention, the WHO QualityRights training

Recently, the World Health Organization (WHO) has developed the QualityRights (QR) training. This training is different from those previously implemented because it applies the modern human rights framework of the UN CRPD and is designed to have people with psychosocial disabilities as central actors in all the activities. People with psychosocial disabilities and their organizations were also actively involved in all the phases of the WHO QR development. The WHO QR intervention includes modules to increase knowledge about the rights of people with psychosocial disabilities and change the negative attitudes towards them and their role as rights holders. Furthermore, the training provides mental health providers with the skills necessary to advocate for a human rights-based approach in mental health and support people with psychosocial disabilities to advocate for their own rights.

Currently, there is a growing interest in the QualityRights training, and the WHO is implementing it in different countries [58]. However, the efficacy of this intervention has not been rigorously evaluated. We have seen that the results of studies conducted in the past (and evaluating interventions with similar objectives) may have been biased due to confounding, selection bias, and information bias issues. To avoid these limitations, when evaluating the efficacy of the WHO QR training, I propose to carry out a cRCT targeting mental health professionals. The use of random assignment to the intervention would help guarantee exchangeability in expectation (at least, at the beginning of the study). The impact of biases due to attrition and non-adherence to the assigned intervention throughout the study should be assessed. A better definition of the outcomes, as well as the use of measures tested for reliability and validity, would also be necessary.

The cRCT I propose will be carried out in Ghana. In Ghana, inhumane practices and violations of persons with psychosocial disabilities' rights are common, as documented by local NGOs and international organizations [59]. In 2012, Ghana enacted a Mental Health Act [60] intended to eliminate the widespread abuses against people with psychosocial disabilities in mental health services and the general community. However, eight years later, violence and abuses against people with psychosocial disabilities are still frequent in the country [9]. To address this situation, the Mental Health Authority of Ghana (Ministry of Health), in partnership with local organizations of people with psychosocial disabilities, expressed an interest in implementing the WHO QualityRights training and are willing to support the conduct of the cRCT here proposed in their country.

Specific aims

To conduct a cRCT in Ghana to determine the efficacy of the QualityRights training compared with a placebo intervention in improving the knowledge about human rights and the attitudes of mental health professionals towards people with psychosocial disabilities and their role as right-holders.

Secondarily, we want also to determine

- if the QualityRights training, compared with a placebo intervention, is effective in changing the practices and experiences related to substitute-decision making and coercion among mental health providers.

The trial's primary hypothesis is that mental health professionals who receive the WHO QualityRights intervention will have a better knowledge about human rights and improved attitudes towards people with psychosocial disabilities and their role as right-holders, compared with their colleagues who receive the placebo intervention. Furthermore, mental health professionals who receive the WHO QualityRights training will resort less to practices related to substitute-decision making and coercion compared with their colleagues who receive the placebo intervention.

2. Significance

2.1 Violations of the human rights of persons with psychosocial disabilities: Dimension of the problem.

People with psychosocial disabilities are commonly exposed to human rights violations both within the mental health care system and in the general community [1-5]. Such violations occur in all countries, although most of the academic research in this field has been carried out in high-income countries [2, 4]. In middle- and low-income countries, our knowledge about this issue is more fragmentary and comes mainly from the media and reports from human rights and other non-governmental organizations [2]. To provide an idea of the gravity and pervasiveness of the problem, I will present an overview of the most common human rights violations against people with psychosocial disabilities: a) discrimination and exclusion from society; b) inability to access adequate mental health services; c) physical, sexual, and psychological abuse, violence, and neglect; and d) denial of the right to legal capacity [2, 4].

(a) Discrimination and exclusion from society.

Many studies have investigated the attitudes and behaviors toward people with psychosocial disabilities. Systematic reviews and meta-analyses provide evidence that discrimination towards this group is widespread and pervasive [61, 62] and results in people with psychosocial disabilities being relegated to the margins of society. For instance, in many countries, children and adolescents with psychosocial disabilities are either institutionalized in facilities that do not provide any education [63, 64] or enrolled in segregated schools or programs, often of poor quality [65-67]. People with psychosocial disabilities are also frequently excluded from the job market. Recent reports show that, within this group, up to 70-90% of people are unemployed in high-income countries [68, 69], while the situation is even worse in low- and middle-income countries [70, 71]. Although there may be times when persons with psychosocial disabilities (as it happens for other disabilities) may not be able to work because of their conditions, so that they may lose their existing jobs or be denied work opportunities, such factors alone cannot explain the high rates of unemployment in this population. More often, the lack of the appropriate accommodations at the workplace make it impossible for people with psychosocial disabilities to perform their jobs and this causes their removal from work [72], with huge socioeconomic effects on their lives [71]. Indeed, the denial of the right to work often causes people with psychosocial disabilities to rely on social security benefits or charity, and this, in turn, tends to perpetuate patterns of dependence and poverty, fostering discrimination and exclusion from society.

All these are just a few examples of the numerous forms of discrimination and exclusion from society faced by people with psychosocial disabilities and result in these persons having limited opportunities for reintegration in

their communities [73-75].

(b) Inability to access effective general and mental health services.

In many countries, people with psychosocial disabilities have limited or no access to general and mental health care [76-78]. Even in high-income countries, where more resources are allocated to health care, the right to (mental) health of people with psychosocial disabilities is far from being respected. Although psychosocial disabilities affect more than a billion persons each year and account for a third of the global burden of disability [79, 80], the mental health budget of most countries is still less than 1 percent of their total health expenditure [81, 82]. Worldwide, more than 70% of the people in need of mental health care do not have access to the appropriate services [83] because these are non-existent or difficult to reach or unaffordable [84, 85]. In the majority of countries, the primary providers of mental health care are psychiatric hospitals [86], where often people with psychosocial disabilities experience poor conditions of the physical infrastructure, inadequate sanitation [87-89], overcrowding, inadequate food [90-92], and administration of obsolete medications [93-95].

(c) Physical, sexual, and psychological abuse, violence, and neglect.

Not only are mental health facilities either difficult to access or of poor quality, but they are also places in which people with psychosocial disabilities are often victims of inhumane treatments, including psychological, physical, and sexual abuse or violence [2, 4, 6, 7]. The prevalence of these violations is high both in high-income and low- and middle-income countries, and thus it cannot be explained simply by a lack of resources [8]. In many mental health facilities, people with psychosocial disabilities continue to be chained to beds or caged for long periods [2, 5, 9-17], verbal abuses by mental health staff are frequent [4, 18-25], and sedation is often implemented for purposes of control [26-32]. Seclusion and restraints are still frequently used [33-37], often as a punishment [38, 39], although they pose severe threats to health and safety [40, 41]. Neglect is another regularly ignored but widespread violation in mental health facilities, where people with psychosocial disabilities are often physically and emotionally abandoned by mental health professionals [6, 87, 96]. Since the mechanisms for monitoring mental health institutions and holding them accountable are usually weak or inexistent, human rights violations within these institutions continue undisturbed, away from the public eye.

Other than in mental health facilities, people with psychosocial disabilities are exposed to psychological, physical, and sexual abuse or violence and neglect in a large variety of contexts. In many low- and middle-income countries, it is common for people with psychosocial disabilities to be abandoned in their family homes, untreated and neglected and, sometimes, even kept in restraints [97, 98]. In high-income countries, people with psychosocial disabilities are frequently victims of domestic violence perpetrated by family members or friends [99, 100]. Furthermore, they are 2.5 times more likely to be assaulted or raped [101], and five times more likely to be victims of homicide [102] than the general population. People with psychosocial disabilities are also more likely to be discriminated against within the criminal justice system so that these crimes often remain unpunished [103].

(d) Denial of the right to legal capacity (including involuntary detention and mandatory treatments).

People with psychosocial disabilities are often deprived of their right to legal capacity (i.e., their right to make decisions), and the authority to make decisions concerning their lives is transferred to a third person, a guardian [47]. Other times, a health practitioner or a family member can be temporarily granted by courts the authority to make specific decisions instead of the person with a psychosocial disability [104]. A guardian or a person appointed by a court can make decisions in all areas of life [105]. These decisions are often based on what is deemed to be in the "best interest" of the persons (i.e., what others think is the best decision for a person) and not on their will and preferences [106, 107]. This extensive resort to substitute-decision making approaches has been shown to have harmful effects on people with psychosocial disabilities and has raised concerns regarding potential abuses of power by the appointed guardians [108]. Nevertheless, the implementation of substitute-decision making models and the use of coercive practices linked to the denial of legal capacity, such as involuntary detentions and mandatory treatments in mental health facilities, are on the rise, even within well-resourced mental health systems [109].

The right to acquire, hold, enjoy, and dispose of property and the right to marry and found a family are also part of the right to legal capacity and are often denied to people with psychosocial disabilities [110, 111], who are also regularly exposed to violations of their political rights. Among the 193 Member States of the United Nations, only twenty-one countries (11%) do not place any legal limitation on the right to vote of persons with psychosocial disabilities [112].

Based on the data collected, the overall evidence is overwhelming that people with psychosocial disabilities continue to experience a wide range of human rights violations, both in high-income and in middle- and low-income countries. We have the moral responsibility to change this situation.

2.2. Violations of the rights of persons with psychosocial disabilities: why are they a public health issue?

The violations of the human rights of persons with psychosocial disabilities are not only a problem from an ethical point of view, but additionally, have profound repercussions on their health. Indeed, the relationship between human rights violations and mental health is complex and bidirectional: psychosocial disabilities make people more vulnerable to human rights violations, and, in a vicious cycle, human rights violations have a negative impact on mental health.

Discrimination and exclusion from society are among the most common human rights violations faced by people with psychosocial disabilities. Numerous systematic reviews document strong and consistent relationships between discrimination and poor mental health [113-116], although there are a few exceptions [117, 118]. Discrimination can also lead to social isolation and exclusion from the community, and these exacerbate mental health conditions and increase mortality in several studies [119]. When individuals realize that other people treat them as if they were less trustworthy, socially inadequate, or unpredictable and dangerous, they act with less confidence and are more defensive with others [120]. This contributes to a shrinking of their social networks and a lowering of their self-esteem, all factors that damage mental well-being and quality of life [121]. People with psychosocial disabilities are also frequently exposed to psychological, physical, and sexual abuse or violence and neglect in a large variety of contexts. Many systematic reviews and meta-analyses show that physical and sexual abuse and violence have both acute and long-term adverse effects on mental health in the general population [122-128]. Although there is still a lack of robust epidemiological research focusing on the impact of psychological, physical, and sexual abuse or violence and neglect in people with psychosocial disabilities, the few existing studies conducted in this specific population show results similar to those found in the general population, providing evidence of a relationship between victimization and poor mental health also in this particular group [129-131].

The denial of the right to property and self-determination in financial matters, the exclusion from education and employment opportunities, and the interference in marital and parental issues are all human rights violations that have a dramatic effect on the distribution of life chances, thus contributing to keep people with psychosocial disabilities in lower socio-economic status groups [132]. Socio-economic status is related to mental health because it influences the exposure of individuals to diseases risks and protective factors [133]. People who have a higher education, more financial resources, power, prestige, and social connections are usually in a better position to avoid diseases and protect their mental health [121, 133]. Since people with psychosocial disabilities, due to the violations of their rights mentioned above, have limited or no access to these resources, they are more exposed to disease risks and are not able to resort to protective strategies. As a result, their mental health is further compromised. To make the situation worse, the services in charge of providing support to people experiencing mental distress and, on a routine basis, to people with psychosocial disabilities, are often inaccessible or are the primary responsible of the human rights violations of the persons they should protect [2, 4, 84, 85].

The mental health sequelae of human rights violations, as well as mental health conditions in general, cannot be treated effectively until the human rights violations stop, and people with psychosocial disabilities can feel safe, respected, and empowered. Since violations often occur within psychiatric facilities, the very institutions responsible for the care and support of people with psychosocial disabilities, it would be fundamental to reform mental health systems if we want to improve this population's health. Particularly, it would be essential to change providers' practices leading to human rights violations, since they are the persons to whom people with psychosocial disabilities turn to when experiencing moments of distress. So far, the violations of the rights of people with psychosocial disabilities have been approached mainly from a social or human rights perspective. However, since they are causes of ill health, we would also need to confront them using a public health perspective. Public health indeed, for its role in the investigation of social determinants of health, development of interventions, and implementation of policies, may provide unique instruments to solve the problem of the violation of people with psychosocial disabilities' rights and improve the health of this population.

2.3. Reasons why these human rights violations continue to be perpetrated within the mental health sector: an analysis of the context in which they happen and the barriers to their elimination

Although mental health and human rights are strictly linked, there has always been – and still there is - a disconnection between the provision of care and the respect and promotion of human rights principles in the mental

health sector [134]. Historically, established practices within mental health facilities have been driven by paternalistic attitudes [135], according to which people with psychosocial disabilities were not capable of making their own decisions, and thus, medical doctors and other health professionals needed to act on their behalf, according to what they assumed was the “best interest” of these persons [47, 136]. Still today, mental health professionals, and in particular psychiatrists, act as substitute decision-makers and have the power, under certain circumstances, to override the “wishes and preferences” of people with psychosocial disabilities [137]. This power has been usually established by law and is largely accepted by the general public, which sees it as necessary to protect individuals from harm [106]. Of course, there may be times when persons with psychosocial disabilities find it challenging to make decisions (but this is true for all people). Indeed, the “ability to make decisions” is not a stable and permanent status. When making decisions becomes difficult, people with psychosocial disabilities have the right to receive support to help them make decisions based on their “will and preferences” [138]. Unfortunately, this often does not happen, and people with psychosocial disabilities are denied their right to make decisions based on their disability status [8]. As a result, substitute-decision making approaches are widely implemented in everyday mental health practice, despite the mounting evidence that they are deleterious and undermine the dignity and well-being of people with psychosocial disabilities, as clearly shown in recent systematic reviews [139, 140] and many narrative reports recording service users’ experiences [141, 142].

When mental health professionals deprive service users of their right to legal capacity (i.e., to make decisions), they often do it with good intentions, driven by the belief that it is their duty to utilize all methods at their disposal to address the patients’ symptomatology or disorders, even if this involves violating their rights [134]. This attitude has resulted in dramatic power imbalances between the psychiatric establishment and the individuals in need of mental health care, often opening the road to further violations and systematic abuses in mental health services and the general community, and fostering the disempowerment of an already marginalized group [8]. This accepted status quo in mental health has been challenged by the United Nations Conventions on the Rights of Persons with Disabilities (UN CRPD) [Appendix 1] [138], which was passed by the United Nations General Assembly in 2006 and, since that date, has been signed and ratified by most of the countries in the world (currently there are 163 signatories and 96 ratifications of the optional protocol) [143]. The UN CRPD has not set out new human rights, but it has established that States have an obligation to respect, protect, and fulfill all the rights of persons with disabilities (including persons with psychosocial disabilities) on an equal basis with others [144]. This would require a paradigm shift in current mental health practice, and thus in mental health professionals’ practices, since it implies that people with psychosocial disabilities cannot be deprived of their rights, including those to legal capacity and liberty (as it happens with substitute decision-making approaches), based on their disability status [145, 146]. Such a revolution in current mental health practice could be paramount in promoting the health of people with psychosocial disabilities and empower them to fight for their rights, not only within mental health services but also in the general community. However, for this to happen, two main barriers need to be addressed.

- **Barrier 1: Lack of literacy on human rights among mental health professionals**

One problem is the lack of human rights literacy among health professionals in general, and thus, also among mental health professionals [42, 43]. There has always been a dearth of communication and collaboration between the health and the human rights fields, due to their different philosophical perspectives, languages, and methods of work [44, 147]. In the past, the health professions has resisted the incorporation of a human rights perspective into its work, wondering about its applicability and utility [147]. This is reflected in the current scarcity of training programs and curricula on human rights in the mainstream education for health professionals and has led to a lack of awareness of service users’ rights and providers’ responsibilities [43]. For instance, a recent survey carried out among Center for Disease Control staff members, working both locally and internationally, has found that 72% of participants did not feel they had adequate knowledge to address human rights in their work, 86% had no knowledge of the criteria for human rights restrictions, and only 2% had received any training on human rights treaties related to their duties [54]. Similar results have been shown in reports and cross-sectional studies carried out among health providers working in Europe [148, 149], Africa [150], Latin-America [151], North-America [152], and other regions [153]. This is alarming since human rights documents inform the duties of health professionals [44], who thus should be familiar with the human rights framework. Such ignorance is even more disturbing if one considers that health professionals (under the guise of protecting the health of individuals) often have the law-sanctioned authority to restrict human rights. This problem is all the more relevant within the mental health care system, where such restrictions are unfortunately not exceptions but the rule.

- **Barrier 2: Negative attitudes towards people with psychosocial disabilities and their role as rights-holders**

One might think that mental health providers, who undergo years of training and have knowledge about mental health issues, would hold positive - or at least neutral - attitudes towards people with psychosocial disabilities. However, many studies demonstrate that this is not true. For instance, Nordt et al. [45] carried out a cross-sectional study showing that mental health professionals, compared with the general public, have a greater desire for social distance from people with a diagnosis of schizophrenia (OR, 3.33; 95% CI, 3.12-3.54) or depression (OR, 2.30; 95% CI, 2.19-2.41). Likewise, a Brazilian nationwide cross-sectional study found that psychiatrists have stronger negative attitudes towards people with a diagnosis of schizophrenia than the general population [46]. Similar findings are shown in several systematic reviews and provide compelling evidence that many mental health professionals hold negative attitudes towards people with psychosocial disabilities [55, 62, 154].

Many mental health practitioners also oppose the complete implementation of a human rights-based approach in mental health, which would require providers to fully respect people with psychosocial disabilities' role as rights-holders, without using their disability as a reason to deny them their human rights in certain circumstances. Overall, currently, there is a consensus among health professionals that a human rights-based approach in the provision of care is necessary and should be enacted since human rights are fundamental for obtaining positive therapeutic outcomes and promoting the well-being of persons [155]. However, in the mental health field, many providers, and especially psychiatrists, have shown resistance to the full integration of such an approach in their everyday practice [134]. The mental health profession is particularly opposed to some human rights principles, listed in the UN CRPD and other international treaties, and underlined in the General Comment on Article 12 of the CRPD [146], which demand to set apart entirely substitute-decision making approaches and the use of coercion – on the basis of disability - in mental health, and move towards a “will and preferences” framework [47]. Indeed, with some exception, providers and their organizations have been resistant to this change and are vehemently opposing it [48-52]. This is happening although both international human rights treaties and the organizations of people with psychosocial disabilities are forcefully demanding the elimination of substitute-decision making and coercion - implemented on the basis of disability - in mental health. Until this happens, people with psychosocial disabilities cannot enjoy any human right, and the systematic abuses in mental health facilities and, consequently, in the general community will go on.

2.4. Potential strategies to remove these barriers and stop the violations of people with psychosocial disabilities' rights: an analysis of the existing interventions and their limitations.

If we want to stop human rights violations against people with psychosocial disabilities in the mental health sector and more broadly, these barriers need to be removed. Thus, it is necessary to educate mental health professionals about human rights and change their negative attitudes towards people with psychosocial disabilities and their role as rights holders. These innovations are necessary to modify mental health professionals' practices leading to violations of the rights of people with psychosocial disabilities. They will also provide professionals with better tools to support people with psychosocial disabilities in advocating for their rights in the broader community.

The full realization of the rights of people with psychosocial disabilities will depend on various stakeholders, including governments, political and judicial bodies, and society as a whole [2]. However, the involvement of these entities can be more effectively achieved if human rights advocates, familiar with mental health issues, are already working on the ground to stop violations. Mental health professionals are in a good position to accomplish these tasks. The focus on mental health professionals is essential since violations often occur within psychiatric institutions, and providers are one of the most resistant groups when it comes to promoting the rights of people with psychosocial disabilities. On the other hand, if we want to change the status quo not only in the mental health context but more broadly in the general community, it is fundamental to support people with psychosocial disabilities in their empowerment to advocate for their own rights. Even in this case, mental health professionals can have a fundamental role and help people with psychosocial disabilities to develop their strengths and skills, including those they may need to advocate for their rights.

We have seen that mental health professionals' lack of knowledge about human rights and negative attitudes are barriers to the elimination of human rights violations against people with psychosocial disabilities. Education about human rights has a fundamental role in removing these barriers. The Knowledge-Attitude-Behavior (KAB) framework [156, 157] helps explain this relationship. According to the KAB framework, the accumulation of knowledge about a particular issue leads to changes in the predisposition to respond (the attitude). Over time, this causes a change in behavior that is in agreement with the attitude [156]. The legitimacy of the KAB approach in the health field, although not entirely free from criticism [158-160], is largely supported by the scientific literature [156, 161-163] and has formed the basis for many successful public health interventions [164-168]. Within our context,

according to the KAB framework, as mental health professionals' knowledge of human rights increases, changes in their attitudes towards people with psychosocial disabilities and their role as rights holders would accumulate. This would lead, over time, to a change in the practices (i.e., the behaviors) leading to violations of the rights of these persons.

Although education on human rights and change in attitudes are interconnected, the interventions aimed to achieve these objectives among mental health professionals have been usually developed to solve only one of these issues at a time. In the next paragraphs, I will describe the initiatives implemented so far in this area and discuss their limitations.

- **Strategy 1 for the elimination of violations: To educate mental health providers about people with psychosocial disabilities' rights.**

In 2005, the UN Special Rapporteur on the Right to Health affirmed that human rights training is fundamental for providing health professionals (including mental health practitioners) with the knowledge and tools to protect and promote human rights in their work [169]. This vision has been strongly endorsed at the international level, and led to the development – still ongoing - of human rights training manuals and capacity-building courses targeting health professionals [43, 53]. A recent review of the literature [43] found that human rights curricula in health professional education use different approaches to increase providers knowledge on this topic, including lectures from academics and experts in the field, group work, individual case studies, journal clubs, and contacts with persons whose rights have been violated. These initiatives have been shown to increase providers' awareness of human rights and, when measured, to improve their attitudes towards marginalized groups [43, 54]. Furthermore, since the promulgation of the UN CRPD, there has been sustained interest over developing trainings or manuals aiming to educate health professionals about the rights of people with psychosocial disabilities, although, so far, most of the materials produced do not target specifically this group [144, 170].

- **Strategy 2 for the elimination of violations: To change mental health professionals' attitudes towards people with psychosocial disabilities and their role as right holders.**

There have been numerous initiatives aimed to challenge the negative attitudes of society towards people with psychosocial disabilities [55, 171, 172]. All these initiatives used distinct educational approaches (e.g., the teaching of skills, social contacts with persons with psychosocial disabilities, engagement in myth-busting) and were evaluated in studies using different designs. Interventions to address stigma among health professionals are uncommon. In a recent systematic review, Henderson et al. [55] examined the effect of anti-stigma programs targeting health professionals (including mental health providers), and identified only 16 studies (three were RCTs, one a previous systematic review, the others were cross-sectional and pre-post intervention studies with or without control) on this topic. Educational trainings delivered by an expert (usually a mental health professional) were the most common type of intervention examined by investigators. Other interventions used internet courses, video presentations, module booklets, or contact-based education projects to address providers' stigma towards people with psychosocial disabilities [55]. Overall, these initiatives were found to be somewhat effective in reducing providers' negative attitudes towards people with psychosocial disabilities.

However, a problem with the existing interventions is that they often do not follow a modern human rights framework (as the one promoted by the UN CRPD). Indeed, these interventions are mainly developed by health practitioners, and thus, they often reflect their perspective, even when this is in contradiction with the CRPD principles and the position of people with psychosocial disabilities. Instead, education on human rights and interventions to address negative attitudes should be based on the modern framework of the UN CRPD and reflect the perspective of people with psychosocial disabilities and their organizations. Another problem concerning the initiatives to address stigma is that they focus on changing mental health professionals' negative attitudes towards people with psychosocial disabilities in general. None of these interventions follows a human-rights based approach and focuses specifically on changing attitudes towards people with psychosocial disabilities' role as rights-holders, although this aspect is fundamental for their full participation in society. Additionally, only a few studies evaluating the impact of human rights training also focused on assessing their ability to change attitudes. However, we assume that improvements in attitudes are an important mediator in the relationship between human rights knowledge and a change in behaviors, our ultimate goal, and thus they should have been more carefully assessed. Even among the studies to address health professionals' stigma, only two [56, 57] assessed a change in behaviors. However, none of them assessed a change in behaviors related to substitute-decision making and coercion.

Another problem is that all the studies [43, 55, 150, 172] evaluating the efficacy of these different interventions present important limitations. Many were pre-post intervention studies, with or without a control group. There is no reason to believe that the observed improvements in knowledge and attitudes would have occurred as

a result of current secular trends, but this cannot be definitively excluded without a control group. Even when the control group was present, most of the studies were non-randomized, and thus we cannot exclude non-comparability between the intervention and the control group. In the few cases where a randomized controlled trial was carried out, the samples enrolled were too small to draw definitive conclusions on the efficacy of the initiatives, and no power calculations were provided. Response rates in many pre-post intervention studies were low, particularly in the post-intervention assessments. This may have caused selection biases. For instance, we could have had a scenario in which the training content was causing loss to follow up (e.g., because the sessions were too lengthy or not engaging) and personal characteristics of participants (e.g., strong endorsement of coercive practices in mental health) were common causes both of the loss to follow up (affecting it positively) and the change in knowledge and attitudes (affecting it negatively). In this case, the results of the studies would have been biased away from the null. Information bias was an issue in many studies since the changes in knowledge and attitudes were evaluated with questionnaires not tested for reliability and validity. No attempt to quantify the impact of these biases was made in any of these studies. Furthermore, only the short-term effect of these programs was usually evaluated (pre-post assessment), and thus, there are no data on more long-term gains. In the future, it would be critical to design methodologically robust studies, carefully conceived to avoid confounding, selection bias, and information bias issues, and with longer follow-ups to evaluate these programs.

2.5. Steps forward: justifying a randomized controlled trial to test the WHO QualityRights training, a new promising intervention

We have seen that many interventions have been implemented in the past to increase mental health professionals' knowledge about human rights and change their attitudes towards people with psychosocial disabilities. Unfortunately, we have also seen that such interventions aimed to achieve only one of these objectives at a time or did not follow a modern human rights framework, like the one promoted by the UN CRPD. Furthermore, none of these interventions assessed a change in health professionals' practices related to substitute-decision making and coercion.

Recently, the World Health Organization (WHO) has launched the QualityRights (QR) initiative [58], which aims to promote the human rights of people with psychosocial disabilities across the globe. As part of the QualityRights initiative, the WHO has developed the QualityRights training. This intervention is different from the ones implemented in the past because it applies the modern framework of the UN CRPD. The QualityRights training includes five modules [see Appendix 2] created to increase the knowledge about the rights of people with psychosocial disabilities and change the negative attitudes towards these persons and their role as rights holders. Furthermore, the training provides mental health providers with the skills necessary to advocate for a human rights-based approach in mental health and support people with psychosocial disabilities to advocate for their rights. This training can be delivered through an online platform and includes presentations, videos, interactive exercises, and forum discussions involving all participants. The discussions are moderated by a multidisciplinary team of coaches, including people with psychosocial disabilities, professionals working in mental health or the disability field, family members, and other stakeholders relevant to the context in which the training is provided. People with psychosocial disabilities and their organizations are central actors in the intervention: They are not only passive recipients but are involved as leaders in all the phases of the training organization and delivery. Another innovative element of the QualityRights training is that people with psychosocial disabilities were actively involved in all the phases of its development, while in the past, such initiatives have reflected only the perspective of mental health professionals.

Currently, there is a growing interest in the QualityRights training, and the WHO is implementing it in different countries [58, 173, 174]. However, the efficacy of this intervention has not been rigorously evaluated. We have seen that the results of studies conducted in the past (and evaluating interventions with kindred objectives) may be biased due to confounding, selection bias, and information bias issues. To avoid these limitations, when evaluating the efficacy of the QualityRights training, I propose to carry out a Randomized Controlled Trial targeting mental health professionals. The use of random assignment to the intervention would help guarantee exchangeability in expectation (at least, at the beginning of the study). Differently from the past, the impact of attrition and non-adherence to the assigned intervention throughout the study should be assessed. Since previous studies usually provided only data on pre-post intervention evaluations, the trial I propose should follow up participants for at least three months, with multiple measures over time (pre-intervention, post-intervention, at three months). A better definition of the outcomes, as well as the use of measures tested for reliability and validity, would also be necessary. Since the assessment of behavioral changes has been neglected in prior research, particular

attention would be given to this area.

Given the impact human rights violations have on the health of people with psychosocial disabilities, an effort is needed to carry out methodologically strong research that will provide robust evidence to support further investment in interventions such as the QualityRights training and make steps forward promoting the rights of people with psychosocial disabilities.

2.6. Why to carry out this cRCT in Ghana?

Recently, Ghana has come under scrutiny for human rights violations against people with psychosocial disabilities, as denounced in several reports by local and international organizations [9, 21, 59]. According to these reports, in psychiatric facilities, Ghanaians with psychosocial disabilities experience poor conditions of the physical infrastructure, insufficient food, and overcrowding. Many residents are forced to live in these institutions against their will and without any possibility to challenge their situation. Verbal and physical abuse are commonly used when persons try to escape, complain about pain, and fail to take medication or follow hospital rules. Unmodified electroconvulsive therapy (i.e., without anesthesia) is used, and people are often isolated in seclusion rooms for up to three days, although such practices constitute ill-treatment and may amount to torture according to the UN special rapporteur on torture. Many people residing in psychiatric facilities spend their days outside the hospital buildings, under the hot sun, with little or no shade and without being engaged in any activity. The situation is no better in the general community, where Ghanaians with a psychosocial disability are frequently believed to be “possessed by evil spirits” or “bewitched” and thus are deemed dangerous [175-177]. As a result, families often send them to traditional or faith-based healing institutions (the so called “prayer camps”) where they are arbitrarily detained for as long as payment to the institution is sustained [9, 21, 59]. Ghanaians with psychosocial disabilities in prayer camps are often chained to trees, frequently in the baking sun, and forced to fast for weeks as part of the “healing process,” while being denied access to medications [9, 21, 59]. Some prayer camps also employ whipping and scarification as a form of treatment [9, 21, 59].

In 2012, to eliminate the widespread human rights violations against people with psychosocial disabilities in mental health facilities and the community, Ghana ratified the UN CRPD and enacted a Mental Health Act [60]. The Act created a Mental Health Authority (Ministry of Health), for which the initial priority was the promotion of the rights of Ghanaians with psychosocial disabilities. To achieve this objective, in February 2019, the Ministry of Health and several Ghanaian organizations of people with psychosocial disabilities launched the “QualityRights in Mental health, Ghana” [178], a project which aims to undertake a country-wide implementation of the WHO QualityRights initiative. As part of this project, they are planning to use the WHO QualityRights online modules to train different stakeholders, including mental health providers, but they would like to evaluate the efficacy of the training before scaling it up at the national level. The cRCT I propose is aligned with this necessity, and the expressed strong policy goals of the government of Ghana.

3. Research Design and Method

3.1 Methodology

- **Aim: To conduct a cRCT in Ghana to determine the efficacy of the QualityRights training compared with a placebo intervention in improving the knowledge about human rights and the attitudes of mental health professionals towards people with psychosocial disabilities and their role as right-holders.**
Secondarily, we want also to determine
 - **if the QualityRights training, compared with a placebo intervention, is effective in changing the practices and experiences related to substitute-decision making and coercion among mental health providers.**

3.1.1 Design

3.1.1.1. Research protocol

The study proposed is part of the project funded by the European Commission (EIDHR 2018-400431) “Empowering persons with psychosocial disabilities to fight for their rights: An implementation of the CRPD and QualityRights principles in Ghana, Lebanon, and Armenia.” The University of Cagliari, in Italy, is the project leader for this project. In Ghana, the project is implemented by the Mental Health Authority - Ministry of Health, the Mental Health Society of Ghana (an organization of persons with psychosocial disabilities), and MindFreedom Ghana (an organization working to promote human rights in mental health). The WHO (Headquarter and Europe Offices) and the Office of the United Nations High Commissioner for Human rights are official partners of the project and are guiding the implementation of the CRPD and QualityRights principles in Ghana. These organizations have been (and will be) involved in all the phases of the study proposed. Approval of the research protocol will be sought by Ethics committees at the Ghana Health Service and Columbia University.

3.1.1.2. Study setting

The trial will be conducted in Ghana. In this country, mental health services are mainly provided in urban areas, either within the three large psychiatric hospitals or in smaller psychiatric units in the three teaching hospitals and five regional hospitals [164]. For this study, participants will be recruited from mental health professionals working in three psychiatric hospitals: Accra, Pantang, and Ankaful. Accra Psychiatric Hospital has a bed capacity of 600 and is located in the Greater Accra Region. Pantang Psychiatric Hospital is a 500-bed hospital also located in the Greater Accra region. Ankaful Psychiatric Hospital is a 350-bed hospital located in the Central Region of Ghana. All three psychiatric hospitals also have outpatient units. They are located in the southern part of the country and serve a population of approximately 25 million persons [179]. Appendix 3 provides further information about the study setting.

3.1.1.3. Study Design

The study will be a cluster Randomized Controlled Trial (cRCT) with hospital units as the clusters to be randomized to the intervention and control arms. Participants will be selected in three steps. First, 28 units (12 from Accra, 12 from Pantang, and 4 from Ankaful) will be randomly selected among the 44 units (19 from Accra, 19 from Pantang, and 6 from Ankaful) of the three psychiatric hospitals for participation in the study. Second, within each of the three psychiatric hospitals, units will be randomized to the intervention and control arms using a 1:1 allocation ratio. The allocation of units will be carried out by an independent researcher based at the University of Cagliari using a computerized randomization sequence. Unit randomization will be completed before the participants are recruited. The local trial coordinator will obtain a letter of permission signed by the Mental Health Authority (Ministry of Health) Chief Executive to access the register of mental health professionals employed in the three psychiatric

hospitals. In each randomized unit, a random sample of potentially eligible mental health professionals identified from the registers will be invited via email or telephone by trained research assistants to be screened for eligibility. Persons who give informed consent to the research assistants to be screened for eligibility will be recruited after confirmation they meet the eligibility criteria for the study. The trained research assistants will be blind to the allocation status to minimize the post-randomization recruitment bias. The recruitment will continue until the planned number of participants is reached. Participants will receive information on the intervention they are assigned to after the baseline collection of data.

3.1.1.4. Eligibility criteria

Inclusion criteria

Participants must be:

1. **Aged 18 years or older.**
2. **Able to speak English.** English is an official language of Ghana and is used as a lingua franca throughout the country. English is also the most used of the eleven official languages spoken in Ghana [179].
3. **Mental health professionals currently working in the in-patient units of the three psychiatric hospitals** (e.g., psychiatrists, psychologists, nurses, occupational therapists, and social workers).

Exclusion criteria

1. **Persons who participated to the in-person WHO QualityRights trainings held in Ghana** (only a small number of mental health professionals working in the three psychiatric hospitals have participated in the in-person training, so selection bias should not be an issue).
2. **Persons enrolled in the online WHO QualityRights training.** The online version of the QualityRights training is available to Ghanaian stakeholders for free. Persons enrolled in the online training at recruitment will be excluded from the study to avoid contamination (only a small number of mental health professionals working in the three psychiatric hospitals have completed the online training, so selection bias should not be an issue).

3.1.1.5. Informed consent procedure

Informed consent will be required at the recruitment by trained research assistants, who will ensure it is administered appropriately. Two levels of consent will be sought from participants: consent to be screened for eligibility and if eligible, consent to participate in the study. A copy of the information sheet and consent form will be sent via e-mail to participants. Re-affirmation of consent will be required before participants complete the questionnaires pre-intervention, post-intervention, and at three months and six months.

In this study, as required by the UN CRPD, individuals' right to legal capacity (including the right to provide informed consent) will not be denied based on disability status. When necessary, participants will receive support tailored to their exigencies, to provide informed consent.

3.1.1.6. Interventions in the study

Intervention arm

Participants assigned to the intervention arm will be enrolled in the QualityRights online training, which aims to increase knowledge about the rights of people with psychosocial disabilities and change negative attitudes towards these persons and their role as rights holders. Furthermore, the training provides mental health professionals with the skills necessary to support people with psychosocial disabilities to advocate for their rights. The QualityRights online training includes five core modules: 1) Human rights; 2) Mental health, disability, and human rights; 3) The right to health and recovery; 4) Legal capacity and the right to decide; 5) Free from coercion, violence, and abuse [see Appendix 2 for further information about the online training topics]. Each module is composed of presentations, videos, interactive exercises, and forum discussions involving all participants. In the forum discussions, particular attention will be given to issues relevant to the Ghanaian context.

The discussions will be moderated by QualityRights trainers selected from a multidisciplinary team, including people with psychosocial disabilities, professionals working in mental health or the disability field, family members, and other local stakeholders.

Control arm

Mental health professionals assigned to the control arm will be enrolled in the WHO novel coronavirus 2019 online training series [see Appendix 4 for further information about the training topics and agenda]. This

trainings series provides a general introduction to COVID-19 and similar respiratory infections and information on what facilities and professionals should be doing to prevent and respond to COVID-19 cases. The training is similar in length to the WHO QualityRights training (12 hours 15 minutes vs. 19 hours) and is intended for health professionals and other stakeholders. To evaluate the integrity of this placebo intervention condition, we will collect information on potential enrollment in the online QualityRights training or other potential interventions at each assessment point.

3.1.1.7. Training of the trainers

Training of the QualityRights trainers was delivered by international WHO consultants with extensive expertise on QualityRights in February 2019. A multidisciplinary team from Ghana, including people with psychosocial disabilities, professionals working in mental health or the disability field, family members, and other local stakeholders, was trained during this event. In March 2019, this pool of new trainers delivered the QualityRights intervention to national and regional stakeholders. The new trainers were supervised by the WHO international consultants and received feedback on their ability to respect topics, time frames, and delivery modalities of the training.

3.1.1.8 Fidelity assessment

The local trial coordinator will participate in the QualityRights forum discussions at least once a week for quality control purposes and provision of detailed feedback. Model fidelity will be evaluated through a checklist investigating adherence to topics and time frames. The local trial coordinator will meet weekly with the project leaders for discussing feedback from the training and ensuring fidelity is respected throughout the entire period of training delivery.

3.1.1.9. Schedule of trial recruitment and participation

Enrollment into the study will commence in 2021. The schedule of enrollment and assessment follow the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) Figure [Appendix 5] [180].

3.2.1.10. Collection of data and Assessment instruments

All the data will be collected through an online platform and made confidential according to the provisions that protect privacy in Europe (Articles 6 and 9 of EU Regulation No. 679) and Ghana (Data Protection Act, 2012).

- The **sociodemographic questionnaire** will include the following information:
 - I. Gender;
 - II. Age in years;
 - III. Educational attainment;
 - IV. Marital status;
 - V. Number of children;
 - VI. Religion;
 - VII. Profession;
 - VIII. Years working in a mental health service;
 - IX. Hospital and unit of work;
 - X. Region of residence;
 - XI. Main language;
 - XII. Family member(s) with a psychosocial disability;
 - XIII. Identification as “person with a psychosocial disability”.

In the case the WHO QualityRights intervention will be found to be not effective, these sociodemographic variables may be used to understand for which subgroups or under what circumstances the training did not work (although this work is outside the scope of the present proposal).

Primary outcomes

- The **World Health Organization’s Knowledge about the Rights of persons with psychosocial disabilities questionnaire** [Appendix 6] (16 items) was developed by WHO to assess knowledge about

the rights included in the UN CRPD. People with psychosocial disabilities had an active role in all the phases of the scale development.

- The **World Health Organization's questionnaire on the attitudes towards people with psychosocial disabilities as rights-holders** [Appendix 7] (17 items) was developed by WHO and includes three subscales: attitudes towards institutionalization and living independently in the community; attitudes toward mandatory treatment and coercion; attitudes toward people with psychosocial disabilities as decision-makers. People with psychosocial disabilities had an active role in all the phases of the scale development.

Secondary outcomes

- The **Practices related to substitute-decision making and coercion scale** [Appendix 8] (12 items) is a scale developed to measure the use of substitute-decision making and coercive practices in mental health units.
- The **Seclusion and Restraint Experience Questionnaire (SREQ)** [Appendix 9] [181] (44 items) was developed to measure emotional and ethical experiences linked to the use of seclusion and restraint among nurses. In this study, an abbreviated version of the scale (25 items), modified for the use among mental health providers, will be used to address seven domains: Negative Experiences, Positive Experiences, Experiences of Control, Experiences of Duty, Experiences of the Misuse of Seclusion and Restraint, Experiences of Seclusion and Restraint as Good Mental Health Practice, Experiences of Ethical Challenge.

The following data will also be collected:

- Information on the enrollment in the online WHO QualityRights training;
- Information on the enrollment in other potential interventions;
- Information on potential contacts with mental health professionals working in other units;
- Information on participants' satisfaction with the course.

The psychometric properties of the WHO's Knowledge about the Rights of persons with psychosocial disabilities questionnaire, the WHO's questionnaire on the attitudes towards people with psychosocial disabilities as rights-holders, and the Practices related to substitute-decision making and coercion scale (the questionnaire I plan to use in Aim 2) have not been tested in Ghana. A description of how we plan to evaluate these instruments' psychometric properties will be made in a separate document.

3.2.1.11 Blinding

Given the nature of the intervention, participants will not be blinded to their intervention arm. However, participants will not be informed of the study hypotheses and will know to which intervention arm they are assigned only after completing the pre-intervention assessment. Data analysts will have access only to anonymized data at the end of each assessment phase. Data will be presented for Group 1 and 2 without the data analysts knowing what 1 and 2 refer to in terms of intervention and control arms.

3.2.1.12 Contamination minimization

The risk of contamination is decreased by the cluster design. The intervention and control unit clusters, although in the same hospital, are distanced and physically separated. The chance of intervention cluster participants regularly meeting control cluster participants is negligible. Furthermore, participants will be asked not to share any information about the intervention they are assigned to with mental health professionals working in other units. Information on potential contacts with mental health professionals working in units allocated to a different arm will be collected at the follow-up interviews to assess the risk and level of contamination.

3.2.1.13 Problems anticipated

The goal of this study is to increase mental health professionals' knowledge about human rights, change their negative attitudes towards people with psychosocial disabilities and their role as rights holders, and change their practices related to substitute-decision making and coercion. The training itself poses no risk to participants. However, the trainers will be provided with skills on how to respond to any participant who may experience distress during the training.

3.2.1.14 Sample size and power calculation

The sample size calculation is based on the following assumptions: two-sided alpha level of 0.05 and power of 0.80. The study group decided that the ability to detect an effect size of 0.5 standard units at the total score at the WHO Organization's questionnaire on the attitudes towards people with psychosocial disabilities as rights-holders between the two groups would be worth finding. The unit of randomization will be the hospital units. The 28 hospitals unit clusters will be randomized with a 1:1 allocation ratio to the intervention or control arm. Based on data from previous cRCT in Ghana [182, 183], we assume a 20% loss to follow-up and ICC=0.05. Based on these assumptions, we calculated that 126 participants would be required in each arm group.

3.1.2 Analysis plan

3.1.2.1 Descriptive analyses.

Descriptive analyses will be conducted for the variables of interest (listed above). Univariate analyses will be used to examine continuous variables by assessing the mean, the median, and the spread of the data. Tabular analyses will be used to examine categorical variables by assessing frequencies. Missing data will be reported for each variable.

3.1.2.2 Approach to missing data.

Based on the descriptive analyses, the most appropriate strategy for accounting for missing data will be chosen. Although this approach does not provide definitive information, the level of missingness and the informativeness of the missing data (i.e., missing completely at random, missing at random, missing not at random) will be assessed by using graphical representation and a statistical assessment to determine if participants with missing data differ appreciably from those without missing data. When appropriate, inverse probability weighting will be used to account for missing data. Sensitivity analyses will be used to evaluate if the results obtained with the inverse probability weighting strategy differ appreciably from the results obtained with a listwise deletion strategy.

3.1.2.3 Main analyses.

An "intent-to-treat" analysis will be used to test the study hypotheses. The primary outcomes of interest will be 1) the change in knowledge about human rights and 2) the change in attitudes of mental health professionals towards people with psychosocial disabilities and their role as right-holders.

Since the data are continuous and longitudinal, linear mixed-effects (LME) regression models will be used to estimate average intervention effects while considering the shared variance of repeated measures and the clustered variance. Correlations arising from repeated measures will be accounted for by specifying an autoregressive covariance structure. Each outcome will be analyzed separately using LME. Time, intervention arm, and their interaction will be included in the model as fixed effects, while participants will be evaluated as random effects. Time will be entered as a categorical variable with levels corresponding to post-training and 3 AND 6 months. The effect of the intervention on the outcomes will be captured by the interaction between intervention and time, which will assess the mean difference between the intervention arms (QR e-training vs. control) in changes of outcomes over time within each group. Effect sizes will be reported as mean differences for each time point and intervention arm, with 95% confidence intervals.

(Random intercept with two group-level covariates and interaction).

Level 1:

$$Y_{ij} = b_{0j} + \varepsilon_{ij}$$

Level 2:

$$b_{0j} = \beta_{00} + \beta_{01}w_j + \beta_{02}t_j + \beta_{03}w_jt_j + b_{0j}^*$$

Combined:

$$Y_{ij} = \beta_{00} + \beta_{01}w_j + \beta_{02}t_j + \beta_{03}w_jt_j + b_{0j}^* + \varepsilon_{ij}$$

- Y_{ij} = attitudes
- β_{00} = "average mean" of units mean attitudes

- b_{0j}^* = difference between specific unit mean attitudes and “average mean” of units mean attitudes
- ε_{ij} = difference between individual attitudes and unit mean attitudes
- t_j = time (3 = at 6 months; 2 = at 3 months; 1 = post – training; 0 baseline)
- w_j = (1 = QR training; 0 control)
- β_{02} = regression coefficient for time
- β_{01} = regression coefficient for unit average attitudes when assigned to QR
- β_{03} = regression coefficient for the interaction of time and intervention

3.1.2.4 Secondary analyses.

Secondary outcomes will be the change in practices and experiences related to substitute-decision making and coercion. The change in practices will be evaluated at three months and six months, while the change in experiences will be evaluated both post-intervention and at three months and six months. These changes will be evaluated using the same methodology already described for the main analyses.

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Appendix 1. United Nations Convention on the Rights of persons with disability

Article 1	Purpose
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Article 13	Access to justice
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Article 23	Respect for home and the family
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Appendix 2. WHO QualityRights e-training modules

Module	Topic	Contents
1	Human rights	This module provides information on what human rights are and the various international human rights documents. In this module, participants learn how different groups, including people with psychosocial disabilities, may be at higher risk of human rights violations and identify ways in which they can respect, protect, and fulfill human rights in their daily lives.
2	Mental health, disability, and human rights	This module provides information on the UN CRPD and, more specifically, on the human rights of persons with psychosocial disabilities. In this module, participants learn to view disability from a human rights perspective, to examine the barriers impeding the full inclusion of people with disabilities in society, and to identify ways to overcome these barriers. Mental health providers learn skills that will help them to support people with psychosocial disabilities to advocate for their rights.
3	The right to health and recovery	This module explains how a human rights-based approach is essential to the recovery of persons with psychosocial disabilities. In this module, participants have discussions about the concepts of mental health, well-being, and the right to health. They also learn the importance of ensuring that people with psychosocial disabilities are central actors in driving their care and recovery journey.
4	Legal capacity and the right to decide	In this module, particular relevance is given to the right to legal capacity and controversial topics such as the ban of substitute-decision making approaches and coercion, both in the mental health sector and in the general community. Emphasis on these problems is fundamental to overcome the division existing between mental health providers and people with psychosocial disabilities on these issues and make them work together for stopping the violations of the rights of the latter.
5	Free from coercion, violence, and abuse	This module provides information on how and why violence, coercion, and abuse occur in mental health settings and the general community. During this workshop, participants learn about the negative impact these practices have on people with psychosocial disabilities and examine the role of power relations in exacerbating violence, coercion, and abuses. Furthermore, participants learn about key strategies and approaches which have been shown to be effective in ending human rights violations within mental health services.

Appendix 3. Study settings

Facilities	Total number of staff	Total number of service users <i>In-patients (per day)</i>	# of inpatients units in the facility
ACCRA PSYCHIATRIC HOSPITAL	823	384	19
ANKAFUL PSYCHIATRIC HOSPITAL	483	146	6
PANTANG PSYCHIATRIC HOSPITAL	486	162	19

**Data provided by the Mental Health Authority, Ministry of Health (Ghana)*

Appendix 4. WHO novel coronavirus 2019 online trainings series

Module	Topic	Contents
1	Introduction to emerging respiratory viruses, including novel coronavirus (3 hours)	This module provides information on COVID-19 and other emerging respiratory viruses.
2	Infection Prevention and Control (IPC) for COVID-19 Virus (1 hour)	This module provides information on infection prevention and control, with a focus on COVID-19. In this module, participants learn how to identify COVID-19 infections and avoid further transmission of the virus in their facilities.
3	Health and safety briefing for respiratory diseases – ePROTECT (2 hours)	This module provides information on acute respiratory infections. In this module, participants learn basic hygiene measures to protect against acute respiratory infections, such as COVID-19.

4	COVID-19: How to put on and remove personal protective equipment (15 min)	This module provides information on the type of personal protective equipment health workers need to correctly protect themselves and on how to use this equipment.
5	Standard precautions: Hand hygiene (1 hour)	This module summarizes the WHO guidelines on hand hygiene and provides information on the associated tools and ideas for effective implementation.
6	Standard precautions: Waste management (1 hour)	This module provides information on waste management strategies to avoid transmission of COVID-19 in health facilities.
7	Standard precautions: Environmental cleaning and disinfection (1 hours)	This module provides information on environmental cleaning and disinfection. In this module, participants learn how cleaning and disinfection prevents contamination of the health care environment.
8	Occupational health and safety for health workers in the context of COVID-19 (1 hour)	This module provides information on occupational health and safety for health workers in the context of COVID-19. In this module, participants learn more about infectious risks to health and safety; physical risks to health and safety; psychosocial risks to health and safety; and basic occupational health and safety in health services.
9	Standard precautions: Injection safety and needle-stick injury management (2 hours)	In this module, participants learn about the causes of unsafe injection practices, how to safely give injections, and how to safely dispose of needles and other sharp instruments.
	<u>Total 12 hours 15 min</u>	

<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/training/online-training>

Appendix 5. Schedule of enrollment, intervention, and assessments

	Recruitment	Pre-Intervention	Post-intervention	Follow-up (3 months)	Follow-up (6 months)
Eligibility criteria	x				
Informed consent	x		x	x	x
Allocation		x			
Socio-demographic questionnaires		x			
WHO's Knowledge about the rights of persons with psychosocial disabilities questionnaire		x	x	x	x
WHO's questionnaire on the attitudes towards people with psychosocial		x	x	x	x

disabilities as rights-holders					
Practices related to substitute-decision making and coercion scale		x		x	x
Abbreviated SREQ		x	x		
Information on the enrollment in the online WHO QualityRights training		x	x	x	
Information on the enrollment in other potential interventions		x	x	x	
Information on contacts with mental health professionals working in units allocated to a different arm		x	x	x	
Information on the satisfaction about the training			x		

Appendix 6. World Health Organization's Knowledge about the Rights of persons with psychosocial disabilities questionnaire

Please indicate if the following statements are True (T) or False (F).

		T	F
1	All 30 human rights within the Universal Declaration of Human Rights (UDHR) are needed to live a good life.		
2	The Universal Declaration of Human Rights (UDHR) is a law.		
3	Human rights can never be restricted.		
4	Violations of human rights can only be carried out by individuals, not by governments.		
5	The Convention on the Rights of People with Disabilities (CRPD) is a convention that protects the rights of all marginalized groups.		
6	According to the CRPD, people with dementia have the right to live in the community and to choose their living arrangements		
7	Informed consent is when a person's family members receive information about		

	different possible treatment options in order to make an informed decision.		
8	Advance plans/directives are documents made by health practitioners to plan in advance the treatment of people using the service.		
9	To promote legal capacity, family members, caregivers, and supporters should help people make decisions by explaining different options but should not assist in communicating decisions to others.		
10			
	Was intended to create new rights for people with disabilities		
	Adopts the medical and charity models of disability		
	Adopts the social and human rights models of disability		
	Is binding on countries which have ratified it		
11			
	Must show their ability to understand rights in order to claim them		
	Have the right to have attitudinal and environmental barriers removed		
	Cannot fully participate in society on an equal basis with others because of attitudinal and environmental barriers		
	Need treatment to 'fix' or heal them		
12			
	People cannot be detained based on the fact that they have a disability		
	People can be detained because they have a disability as long as other criteria such as dangerousness or medical necessity are also met		
	People with disabilities can only be deprived of liberty for the same reasons as any other person		
	Mental health laws can authorise people to be detained if they are diagnosed with a mental health condition and if they are perceived as dangerous		
13			
	Can be declined by the person		
	Requirements may vary throughout life		
	Should concern only complex decisions		
	Should increase throughout life		
14			
	Keep people safe		
	Are forms of coercion		
	Improve recovery if used correctly		
	Can cause harm		
15			
	User –led recovery and/or treatment plans		
	Healthcare provider-led recovery and/or treatment plans		
	Informed consent		
	Substitute-decision making		
16			
	Governments must make sure that people with disabilities are free from torture or cruel, inhuman or degrading treatment or punishment		
	The use of restraints is only allowed in cases where the service lacks adequate human resources		
	Countries must make laws to ensure that people with disabilities are protected from exploitation, violence and abuse in the home and in the community		
	There is no need to make laws to protect people with disabilities from exploitation, violence and abuse because the CRPD already ensures their protection		

Appendix 7. World Health Organization’s questionnaire on the attitudes towards people with psychosocial disabilities as rights-holders

Please indicate your level of agreement with the following statements.
Select only one option for each statement.

		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1.	Nothing can be improved within mental health services without additional resources.					
2.	The service environment has little to do with people's mental health and well-being.					
3.	People with dementia should always live in group homes where staff can take care of them					
4.	People with psychosocial disabilities/mental health conditions should not be hired in work requiring direct contact with the public.					
5.	Taking medication is the most important factor to help people with mental health conditions get better.					

		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
6.	You can only inspire hope once a person is no longer experiencing symptoms					
7.	People using mental health services should be empowered to make their own decisions about their treatment.					
8.	Following advice of other people who have experienced mental health issues is too risky.					
9.	The opinions of health practitioners about care and treatment should carry more weight than those of a person with an intellectual disability.					
10.	It is acceptable to pressure people using mental health services to take treatment that they don't want.					
11.	Persons with mental health conditions should not be given important responsibilities.					
12.	When people experience a crisis, health practitioners or families should make decisions based on their ideas about what is best for them.					
13.	People with intellectual disabilities have the right to make their own decisions, even if I don't agree with them.					
14.	Controlling people using mental health services is necessary to maintain order.					
15.	The use of seclusion and restraint is needed if people using mental health services become threatening.					
16.	People at risk of harming themselves or others should be isolated in a locked room.					
17.	Involuntary admission does more harm than good.					

Appendix 8. The Practices related to substitute-decision making and coercion questionnaire.

Please indicate how many times in the last month you used the following strategies **within your psychiatric unit**.

Select only one option for each statement.

		<i>Every day</i>	<i>A few times a week</i>	<i>Once a week</i>	<i>A few times a month</i>	<i>Once a month or less</i>	<i>A few times in the last three months</i>	<i>Never</i>
1	I used seclusion (for instance, ordering or keeping service users in a locked room)							
2	I used physical restraints (for instance, using ties or other mechanical devices to restrain service users)							
3	I prescribed or administered a treatment although the service user did not want it							
4	I supported service users to write their recovery plan							
5	I informed service users about their rights (including their right to refuse treatment)							
6	I used chemical restraints (for instance, prescribing or administering an injection to calm the behavior of service users without their consent)							
7	I yelled or used verbal aggression to get service users to comply with requests							

For each statement, mark the box that most accurately reflects your response.

		A lot less than me	Less than me	As much as me	More than me	A lot more than me
8	Mental health professionals in my unit use seclusion and physical/chemical restraints					
9	Mental health professionals in my unit yell or use verbal aggression to get service users to comply with requests					
10	Mental health professionals in my unit prescribe or administer treatments to control the behavior of service users					
11	Mental health professionals in my unit respect the will and preferences of service users					
12	Mental health professionals in my unit use restraints to control unsettled situations in the ward					

Appendix 9. Seclusion and Restraint Experience Questionnaire (SREQ)

	Strongly disagree	Somewhat disagree	Somewhat agree	Strongly agree
Negative experiences				

1) I feel anguish when S/R the patient				
2) I feel guilty when S/R the patient				
3) I feel angry toward the patient when implementing S/R				
4) The S/R of the patient causes me regret afterwards				
5) I feel pity toward the patient in S/R situations				
Positive experiences				
6) S/R the patient is a relieving experience				
7) S/R of the patient increases my experiences of safety				
Experiences of control				
8) S/R is an acceptable way to control an unsettled situation on the ward				
9) S/R is a way to control a patient who acts harmfully to others				
10) S/R is a way to maintain the safety of the mental health staff				
Experiences of duty				
11) S/R is integral to psychiatric care				
12) S/R is an attempt to guarantee the safety of the patients				
Experiences of misuse of the S/R				
13) S/R have been used too often on my ward				
14) The patient stays in S/R too long				
15) S/R have been used as a punishment				
16) Alternatives to minimize the use of S/R have not been used as much as possible				
17) There are different opinions about the need to use S/R on my ward				
18) The patient can be secluded or restrained because of the few amount of mental health professionals of the ward				
Seclusion or restraint as good mental health practice				
19) S/R is an acceptable intervention to control the patient who strains the mental health staff				
20) Alternative methods can not totally replace the use of S/R				
21) I help the patient with S/R				
22) S/R should not be used at all				
23) All alternative methods should be tried before using S/R				

Experiences of Ethical challenges				
24) It is difficult to find alternative methods to S/R				
25) S/R violates the autonomy of the patient				