UPSIDES RCT

Informed Consent Forms

The study “Using Peer Support in Developing Empowering Mental Health Services: pragmatic multicentre randomised controlled trial with embedded cost-effectiveness analysis and process evaluation” (UPSIDES RCT) involves different study designs (quantative and qualitative) for different target groups. Thus, different informed consent forms are needed. This document provides templates for obtaining informed consent of participants of these studies. All templates have been drafted in line with the WHO informed Consent Form Template for Clinical Studies (www.who.int/rpc/research_ethics/InformedConsent- clinicalstudies.doc), and have been checked and approved by UPSIDES ethics advisor Dr. Felicitas Söhner. We recommend that all participating sites use these informed consent forms, after translating them to the local languages. For any changes or amendments should be necessary, please contact the Coordinating Centre at Ulm University.

Contents

1. Quantitative data to be collected from service users

(covering sections 1, 2 and 3.1 of the study protocol)

[INSTITUTIONAL LETTERHEAD]

This informed consent for is for adults with severe mental illness who are invited to participate in the research project "Using Peer Support in Developing Empowering Mental Health Services: pragmatic multicentre randomised controlled trial with embedded process evaluation and cost-effectiveness analysis" (short UPSIDES RCT).

[Name of Principal Investigator]
[Name of Organisation]

This Informed Consent Form has two parts:

- Information Sheet (to share information about the research with you)
- Certificate of consent (for signatures if you agree to take part)

You will be given a copy of the full Informed Consent Form.

1.1. PART I: Information Sheet

Introduction

I am a researcher from [Name of Organisation] doing research on mental illness and how to improve mental health care. Thank you for taking your time to let us inform you about the UPSIDES project about peer support for people with severe mental illness. I will now further explain to what the project is about and I would like to invite you to participate. First of all, I would like to point out that you do not need to decide right away whether or not you will participate in the study. Before you decide, you can talk to anyone you feel comfortable with about the research. This study information form may contain words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me or another researcher.

Purpose of the research

A large number of people with severe mental illness do not receive any treatment. This has severe effects on the people affected themselves and our society in total. Peer support may be a possibility to reduce the negative effects. Here, a person in recovery from mental illness offers support to other people with mental illness. A peer support worker acts as a mentor and promotes the service users's journey towards recovery. We want to find out whether peer support helps service users improve social inclusion and reduces illness severity.

Type of Research Intervention

This study compares peer support, i.e. support given by a person with lived experience of mental illness who has received training in UPSIDES peer support to a person with mental illness, to usual care.

Participant selection

We are inviting all adults with severe mental illness in [Name of institution or catchment area] to participate in this research on peer support.

Questions to elucidate understanding: "Do you know why we are asking you to take part in this study?" "Do you know what the study is about?"

Voluntary Participation

Your participation in this research is entirely voluntary. You can withdraw your consent to participate at any time without having to give any reasons. Withdrawal of consent will not result in any loss of benefits. There will be no effects of withdrawal whatsoever on your further medial care. You may change your mind later and stop participating even if you agreed earlier.

Questions to elucidate understanding: "If you decide not to take part in this research study, do you

know what your options are?" "Do you know that you do not have to take part in this research study, if you do not wish to?" "Do you have any questions?"

Procedures and Protocol

Participation in UPSIDES RCT means that you will meet with an UPSIDES research worker four times over one year (every four months) to give him/her general information about yourself (e.g. age, gender, family situation, work) and about your mental health problems. These interviews will last for about 1 1/2 hours each.

This is a randomised controlled trial which means that after having consented to participation, you will be allocated per chance (50:50) to the intervention or control group. If you are allocated to the intervention group, you will receive UPSIDES peer support. This service will be provided by a trained UPSIDES peer support worker who has also experienced mental ill health and will support your recovery. If you are allocated to the control group, your participation will involve data assessment as described above. However, as this is a waiting list design, control group participants will receive the intervention in one year.

Risks and benefits of study participation

If you agree to participate, we will ask questions on your health and mental health during our four meetings in one year. Four meetings will require your time as per our interview schedule. This could potentially place a burden on you. If you are allocated to the intervention group, you will receive the intervention immediately. If you are in the control group, you will receive the intervention in one year.

Question to elucidate understanding: "Can you tell me if you remember the number of times that we are asking you to give information on your health status?" "What is peer support?" "Do you have any other questions?" "Do you want me to go through the procedures again?"

Reimbursements

You will receive [insert number and currency] for study participation ([insert number and currency] for each completed assessment). Furthermore, your expenses for travelling to the research centre and back home for study participation will be reimbursed as per site-based policies.

Insurance

You will be insured for accidents for travelling to the research centre and back home for study participation based on site-based requirements [specify requirements as needed].

Confidentiality

Your data will be stored safely at the study centre for the entire duration of the study. Data transfer via internet will be encrypted using the highest standards. Only research staff and representatives of the local ethics committee will have access to individual study data. All people with access to the data are bound to professional discretion. Confidentiality of records will be maintained by assigning an ID to each participant. There will be only one list where participant ID data is stored together with the participant's name and address. This file will be stored safely and kept separate from the data used for analyses. Any personal information that could identify you will be removed or changed before files are shared with other researchers or results are made public. You are entitled to access your personal data and ask questions about them at the study centre at any time, provided a research worker is there to show you how to do that and give answers to your questions.

Sharing the results

The knowledge that we get from doing this research will be published in order that other interested people may learn from our research. You may get information about the results at www.upsides.org. You may contact the study centre at any time and ask questions about the results from this research.

Right to refuse or withdraw

I would like to make clear to you again that your participation in UPSIDES RCT is voluntary. You can withdraw your consent to participate at any time without having to give any reasons. Withdrawal of consent will not result in any loss of benefits. There will be no effects of withdrawal

whatsoever on your further medial care.

Who to contact
During the time of your study participation and beyond you can contact the research centre at any time in case of any questions. Your contact person at [insert institution] will be [insert name], to be reached via phone [insert phone number] or e-mail [insert e-mail-address]. This is also the person who you can tell that you do not want to take part in this study.

This proposal has been reviewed and approved by [name of the local IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [name, address, telephone number])

Questions to elucidate understanding: "Do you know that you do not have to take part in this study if you do not wish to?" "You can say No if you wish to?" "Do you know that you can ask me questions later, if you wish to?" "Do you know that I have given the contact details of the person who can give you more information about the study?"

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

1.2. PART II: Certificate of consent

I have read the foregoing information, or it has been read to me by [insert name of research worker]. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print name of participant _____

Signature of participant _____

Date _____
Day/month/year

If illiterate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ **AND** **Thumb print of participant**

Signature of witness _____

Date _____
Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

(1) The participant will meet with an UPSIDES research worker four times over one year (every four months) to give general information about yourself (e.g. age, gender, family situation, work) and about his or her mental and general health status.
(2) The participant will be allocated per chance to the intervention or control group. If he or she is allocated to the intervention group, he or she will receive UPSIDES peer support.
(3) If he or she is allocated to the control group, he or she will receive the intervention at a later point in time.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant.

Print Name of Researcher/person taking the consent _____

Signature of Researcher /person taking the consent _____

Date _____
Day/month/year

2. Quantitative data to be collected from UPSIDES peer support workers

(covering section 3.1 of the study protocol)

[INSTITUTIONAL LETTERHEAD]

This informed consent for is for peer support workers providing UPSIDES peer support to service users who are invited to participate in the research project "Using Peer Support in Developing Empowering Mental Health Services: pragmatic multicentre randomised controlled trial with embedded process evaluation and cost-effectiveness analysis" (short UPSIDES RCT).

[Name of Principal Investigator]
[Name of Organisation]

This Informed Consent Form has two parts:

- Information Sheet (to share information about the research with you)
- Certificate of Consent (for signatures if you agree to take part)

You will be given a copy of the full Informed Consent Form.

2.1. PART I: Information Sheet

Introduction

I am a researcher from [Name of Organisation] doing research on mental illness and how to improve mental health care. Thank you for taking your time to let us inform you about the UPSIDES project about peer support for people with severe mental illness. I will now further explain to what the project is about and I would like to invite you to participate. First of all I would like to point out that you do not need to decide right away whether or not you will participate in the study. Before you decide, you can talk to anyone you feel comfortable with about the research. This study information form may contain words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me or of another researcher.

Purpose of the research

A large number of people with severe mental illness do not receive any treatment. This has severe effects on the people affected themselves and our society in total. Peer support may be a possibility to reduce the negative effects. Here, a person in recovery from mental illness offers support to other people with mental illness. A peer support worker acts as a mentor and promotes the service users's journey towards recovery. We want to find out about the effects of providing UPSIDES peer support on peer support workers.

Type of Research Intervention

This study assesses peer support, i.e. support given by a person with lived experience of mental illness who has received training in UPSIDES peer support to a person with mental illness.

Participant selection

We are inviting all peer support workers providing UPSIDES peer support in [Name of institution or catchment area] to participate in this research.

Questions to elucidate understanding: "Do you know why we are asking you to take part in this study?" "Do you know what the study is about?"

Voluntary Participation

Your participation in this research is entirely voluntary. You can withdraw your consent to participate at any time without having to give any reasons. Withdrawal of consent will not result in any loss of benefits. There will be no effects of withdrawal whatsoever on your further medial care. You may change your mind later and stop participating even if you agreed earlier.

Questions to elucidate understanding: "If you decide not to take part in this research study, do you know what your options are?" "Do you know that you do not have to take part in this research study,

if you do not wish to?" "Do you have any questions?"

Procedures and Protocol
Participation in this study means that you will complete a number of questionnaires while working as a peer support worker in the UPSIDES project. These questionnaires will be about your experiences with peer support with an individual service user (two measurement points per service user, about 15 min. each), and about the effects on you of providing UPSIDES peer support (three measurement points before, during and after you provide UPSIDES peer support, about 30 min each). You may complete the questionnaires together with an UPSIDES research worker or on your own.

Risks and benefits of study participation
If you decide to participate, we will ask questions about your experiences with UPSIDES peer support during one year. The meetings will require your time as per our interview schedule. This could potentially place a burden on you.

Question to elucidate understanding: "Can you tell me if you remember the number of times that we are asking you to give information on your health status?" "Do you have any other questions?" "Do you want me to go through the procedures again?"

Reimbursements
You will receive [insert number and currency] for study participation ([insert number and currency] for each completed assessment). Furthermore, your expenses for travelling to the research centre and back home for study participation will be reimbursed as per site-based policies.

Insurance
You will be insured for accidents for travelling to the research centre and back home for study participation based on site-based requirements [specify requirements as needed].

Confidentiality
Your data will be stored safely at the study centre for the entire duration of the study. Data transfer via internet will be encrypted using the highest standards. Only research staff and representatives of the local ethics committee will have access to individual study data. All people with access to the data are bound to professional discretion. Confidentiality of records will be maintained by assigning an ID to each participant. There will be only one list where participant ID data is stored together with the participant's name and address. This file will be stored safely and kept separate from the data used for analyses. Any personal information that could identify you will be removed or changed before files are shared with other researchers or results are made public. You are entitled to access your personal data and ask questions about them at the study centre at any time, provided a research worker is there to show you how to do that and give answers to your questions.

Sharing the results
The knowledge that we get from doing this research will be published in order that other interested people may learn from our research. You may get information about the results at www.upsides.org. You may contact the study centre at any time and ask questions about the results from this research.

Right to refuse or withdraw
I would like to make clear to you again that your participation in UPSIDES RCT is voluntary. You can withdraw your consent to participate at any time without having to give any reasons. Withdrawal of consent will not result in any loss of benefits. There will be no effects of withdrawal whatsoever on your further medial care.

Who to contact
During the time of your study participation and beyond you can contact the research centre at any time in case of any questions. Your contact person at [insert institution] will be [insert name], to be reached via phone [insert phone number] or e-mail [insert e-mail-address]. This is also the person who you can tell that you do not want to take part in this study.

This proposal has been reviewed and approved by [name of the local IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [name, address, telephone number])

Questions to elucidate understanding: "Do you know that you do not have to take part in this study if you do not wish to?" "You can say No if you wish to?" "Do you know that you can ask me questions later, if you wish to?" "Do you know that I have given the contact details of the person who can give you more information about the study?"

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

2.2. PART II: Certificate of consent

I have read the foregoing information, or it has been read to me by [insert name of research worker]. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print name of participant _____

Signature of participant _____

Date _____
Day/month/year

If illiterate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ **AND** **Thumb print of participant**

Signature of witness _____

Date _____
Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

(1) The participant will complete two assessments per service user reporting about his experiences with providing UPSIDES peer support to a particular service user.
(2) The participant will complete three assessments (before, during and after the intervention) reporting about effects on him-/herself of providing UPSIDES peer support.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant.

Print Name of Researcher/person taking the consent _____

Signature of Researcher /person taking the consent _____

Date _____
Day/month/year

3. Qualitative data to be collected from service users

(covering section 3.2.1 of the study protocol).

[INSTITUTIONAL LETTERHEAD]

This informed consent for is for people with mental illness who have received UPSIDES peer support who are invited to participate in the research project "Using Peer Support in Developing Empowering Mental Health Services: pragmatic multicentre randomised controlled trial with embedded process evaluation and cost-effectiveness analysis" (short UPSIDES RCT).

[Name of Principal Investigator]
[Name of Organisation]

This Informed Consent Form has two parts:

- Information Sheet (to share information about the research with you)
- Certificate of Consent (for signatures if you agree to take part)

You will be given a copy of the full Informed Consent Form.

3.1. PART I: Information Sheet

Introduction

I am a researcher from [Name of Organisation] doing research on mental illness and how to improve mental health care by using mental health peer support. Thank you for taking your time to let us inform you about the UPSIDES project about peer support for people with severe mental illness. I will now further explain to what the project is about and I would like to invite you to participate. First of all I would like to point out that you do not need to decide right away whether or not you will participate in the study. Before you decide, you can talk to anyone you feel comfortable with about the research. This study information form may contain words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me or of another researcher.

Purpose of the research

A large number of people with severe mental illness do not receive any treatment. This has severe effects on the people affected themselves and our society in total. Peer support may be a possibility to reduce the negative effects. Here, a person in recovery from mental illness offers support to other people with mental illness. A peer support worker acts as a mentor and promotes the service users's journey towards recovery. We want to learn more about peer support from the people involved in these services. Thus, we want to find out your views and experiences on receiving peer support including positive and negative perceptions. In addition, we want to learn from your experiences about facilitators and barriers to the implementation of peer support.

Type of Research Intervention

This study assesses peer support, i.e. support given by a person with lived experience of mental illness who has received training in UPSIDES peer support to a person with mental illness.

Participant selection

We are inviting 6-8 service users who have received UPSIDES peer support in [Name of institution or catchment area] to participate in this research.

Questions to elucidate understanding: "Do you know why we are asking you to take part in this study?" "Do you know what the study is about?"

Voluntary Participation

Your participation in this research is entirely voluntary. You can withdraw your consent to participate at any time without having to give any reasons. Withdrawal of consent will not result in any loss of benefits. There will be no effects of withdrawal whatsoever on your further medial care. You may change your mind later and stop participating even if you agreed earlier.

Questions to elucidate understanding: "If you decide not to take part in this research study, do you know what your options are?" "Do you know that you do not have to take part in this research study, if you do not wish to?" "Do you have any questions?"

Procedures and Protocol
Participation in this study means that you will be asked to meet with an UPSIDES research worker for an interview shortly after having received UPSIDES peer support. The interview will last for about 30-60 minutes, depending on your preferences. The interview will be recorded and will be put down in writing with anonymization of any identifying information about you or named third parties.

Risks and benefits of study participation
If you decide to participate, your study participation means that you will be interviewed for 30-60 minutes by an UPSIDES research worker. Such an interview may place a burden on some participants.

Question to elucidate understanding: "Do you have any other questions?" "Do you want me to go through the procedures again?"

Reimbursements
You will receive [insert number and currency] for study participation ([insert number and currency] for each completed assessment). Furthermore, your expenses for travelling to the research centre and back home for study participation will be reimbursed as per site-based policies.

Insurance
You will be insured for accidents for travelling to the research centre and back home for study participation based on site-based requirements [specify requirements as needed].

Confidentiality
Your data will be stored safely at the study centre for the entire duration of the study. Data transfer via internet will be encrypted using the highest standards. Only research staff and representatives of the local ethics committee will have access to individual study data. All people with access to the data are bound to professional discretion. Confidentiality of records will be maintained by assigning an ID to each participant. There will be only one list where participant ID data is stored together with the participant's name and address. This file will be stored safely and kept separate from the data used for analyses. Any personal information that could identify you will be removed or changed before files are shared with other researchers or results are made public. You are entitled to access your personal data and ask questions about them at the study centre at any time, provided a research worker is there to show you how to do that and give answers to your questions.

Sharing the results
The knowledge that we get from doing this research will be published in order that other interested people may learn from our research. You may get information about the results at www.upsides.org. You may contact the study centre at any time and ask questions about the results from this research.

Right to refuse or withdraw
I would like to make clear to you again that your participation in UPSIDES RCT is voluntary. You can withdraw your consent to participate at any time without having to give any reasons. Withdrawal of consent will not result in any loss of benefits. There will be no effects of withdrawal whatsoever on your further medial care.

Who to contact
During the time of your study participation and beyond you can contact the research centre at any time in case of any questions. Your contact person at [insert institution] will be [insert name], to be reached via phone [insert phone number] or e-mail [insert e-mail-address]. This is also the person who you can tell that you do not want to take part in this study.

This proposal has been reviewed and approved by [name of the local IRB], which is a

committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [name, address, telephone number])

Questions to elucidate understanding: "Do you know that you do not have to take part in this study if you do not wish to?" "You can say No if you wish to?" "Do you know that you can ask me questions later, if you wish to?" "Do you know that I have given the contact details of the person who can give you more information about the study?"

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

3.2. PART II: Certificate of consent

I have read the foregoing information, or it has been read to me by [insert name of research worker]. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print name of participant _____

Signature of participant _____

Date _____
Day/month/year

If illiterate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ **AND** **Thumb print of participant**

Signature of witness _____

Date _____
Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

The participant will be interviewed for about one hour about his or her experiences with UPSIDES peer support after having received the intervention.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant.

Print Name of Researcher/person taking the consent _____

Signature of Researcher /person taking the consent _____

Date _____
Day/month/year

4. Qualitative data to be collected from UPSIDES peer support workers

(covering section 3.2.2 of the study protocol).

[INSTITUTIONAL LETTERHEAD]

This informed consent for is for peer support workers who have provided UPSIDES peer support to service users who are invited to participate in the research project "Using Peer Support in Developing Empowering Mental Health Services: pragmatic multicentre randomised controlled trial with embedded process evaluation and cost-effectiveness analysis" (short UPSIDES RCT).

[Name of Principal Investigator]
[Name of Organisation]

This Informed Consent Form has two parts:

- Information Sheet (to share information about the research with you)
- Certificate of Consent (for signatures if you agree to take part)

You will be given a copy of the full Informed Consent Form.

4.1. PART I: Information Sheet

Introduction

I am a researcher from [Name of Organisation] doing research on mental illness and how to improve mental health care. Thank you for taking your time to let us inform you about the UPSIDES project about peer support for people with severe mental illness. I will now further explain to what the project is about and I would like to invite you to participate. First of all I would like to point out that you do not need to decide right away whether or not you will participate in the study. Before you decide, you can talk to anyone you feel comfortable with about the research. This study information form may contain words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me or of another researcher.

Purpose of the research

A large number of people with severe mental illness do not receive any treatment. This has severe effects on the people affected themselves and our society in total. Peer support may be a possibility to reduce the negative effects. Here, a person in recovery from mental illness offers support to other people with mental illness. A peer support worker acts as a mentor and promotes the service users's journey towards recovery. We want to find out about UPSIDES peer support workers' views on their occupational roles, facilitators and barriers, as well as resources and needs.

Type of Research Intervention

This study assesses peer support, i.e. support given by a person with lived experience of mental illness who has received training in UPSIDES peer support to a person with mental illness.

Participant selection

We are inviting 3-7 peer support workers who have provided UPSIDES peer support in [Name of institution or catchment area] to participate in one of two groups, one for women and one for men.

Questions to elucidate understanding: "Do you know why we are asking you to take part in this study?" "Do you know what the study is about?"

Voluntary Participation

Your participation in this research is entirely voluntary. You can withdraw your consent to participate at any time without having to give any reasons. Withdrawal of consent will not result in any loss of benefits. There will be no effects of withdrawal whatsoever on your further medial care. You may change your mind later and stop participating even if you agreed earlier.

Questions to elucidate understanding: "If you decide not to take part in this research study, do you know what your options are?" "Do you know that you do not have to take part in this research study,

if you do not wish to?" "Do you have any questions?"

Procedures and Protocol
Participation in this study means that, after having provided UPSIDES peer support, you will be asked to meet with 2-6 other UPSIDES peer support workers of the same gender as you for a group interview (also called focus group). The focus group be organised by two with UPSIDES research workers and will last for about one hour. The interview will be recorded and will be put down in writing with anonymization of any identifying information about you or named third parties.

Risks and benefits of study participation
If you decide to participate, your study participation means that you will be interviewed for about one hour by an UPSIDES research worker together with other with other peer support workers. Such an interview may place a burden on some participants.

Question to elucidate understanding: "Do you have any other questions?" "Do you want me to go through the procedures again?"

Reimbursements
You will receive [insert number and currency] for study participation ([insert number and currency] for each completed assessment). Furthermore, your expenses for travelling to the research centre and back home for study participation will be reimbursed as per site-based policies.

Insurance
You will be insured for accidents for travelling to the research centre and back home for study participation based on site-based requirements [specify requirements as needed].

Confidentiality
Your data will be stored safely at the study centre for the entire duration of the study. Data transfer via internet will be encrypted using the highest standards. Only research staff and representatives of the local ethics committee will have access to individual study data. All people with access to the data are bound to professional discretion. Confidentiality of records will be maintained by assigning an ID to each participant. There will be only one list where participant ID data is stored together with the participant's name and address. This file will be stored safely and kept separate from the data used for analyses. Any personal information that could identify you will be removed or changed before files are shared with other researchers or results are made public. You are entitled to access your personal data and ask questions about them at the study centre at any time, provided a research worker is there to show you how to do that and give answers to your questions.

Sharing the results
The knowledge that we get from doing this research will be published in order that other interested people may learn from our research. You may get information about the results at www.upsides.org. You may contact the study centre at any time and ask questions about the results from this research.

Right to refuse or withdraw
I would like to make clear to you again that your participation in UPSIDES RCT is voluntary. You can withdraw your consent to participate at any time without having to give any reasons. Withdrawal of consent will not result in any loss of benefits. There will be no effects of withdrawal whatsoever on your further medial care.

Who to contact
During the time of your study participation and beyond you can contact the research centre at any time in case of any questions. Your contact person at [insert institution] will be [insert name], to be reached via phone [insert phone number] or e-mail [insert e-mail-address]. This is also the person who you can tell that you do not want to take part in this study.

This proposal has been reviewed and approved by [name of the local IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [name, address, telephone

number])

Questions to elucidate understanding: "Do you know that you do not have to take part in this study if you do not wish to?" "You can say No if you wish to?" "Do you know that you can ask me questions later, if you wish to?" "Do you know that I have given the contact details of the person who can give you more information about the study?"

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

4.2. PART II: Certificate of consent

I have read the foregoing information, or it has been read to me by [insert name of research worker]. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print name of participant _____

Signature of participant _____

Date _____
Day/month/year

If illiterate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ **AND** **Thumb print of participant**

Signature of witness _____

Date _____
Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

The participant will participate for about one hour in a focus group interview about his or her experiences with UPSIDES peer support.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant.

Print Name of Researcher/person taking the consent _____

Signature of Researcher /person taking the consent _____

Date _____
Day/month/year

5. Qualitative data to be collected from mental health workers

(covering section 3.2.3 of the study protocol)

[INSTITUTIONAL LETTERHEAD]

This informed consent for is for mental health workers who will be in contact with UPSIDES peer support workers and service users who are invited to participate in the research project "Using Peer Support in Developing Empowering Mental Health Services: pragmatic multicentre randomised controlled trial with embedded process evaluation and cost-effectiveness analysis" (short UPSIDES RCT).

[Name of Principal Investigator]
[Name of Organisation]

This Informed Consent Form has two parts:

- Information Sheet (to share information about the research with you)
- Certificate of Consent (for signatures if you agree to take part)

You will be given a copy of the full Informed Consent Form.

5.1. PART I: Information Sheet

Introduction

I am a researcher from [Name of Organisation] doing research on mental illness and how to improve mental health care. Thank you for taking your time to let us inform you about the UPSIDES project about peer support for people with severe mental illness. I will now further explain to what the project is about and I would like to invite you to participate. First of all I would like to point out that you do not need to decide right away whether or not you will participate in the study. Before you decide, you can talk to anyone you feel comfortable with about the research. This study information form may contain words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me or of another researcher.

Purpose of the research

A large number of people with severe mental illness do not receive any treatment. This has severe effects on the people affected themselves and our society in total. Peer support may be a possibility to reduce the negative effects. Here, a person in recovery from mental illness offers support to other people with mental illness. A peer support worker acts as a mentor and promotes the service users's journey towards recovery. We want to find out the impact of UPSIDES peer support on the individual clinician, on the multidisciplinary teams, and on the service user. We also want to find out about factors that helped or hindered the successful implementation of peer support in your team.

Type of Research Intervention

This study assesses peer support, i.e. support given by a person with lived experience of mental illness who has received training in UPSIDES peer support to a person with mental illness.

Participant selection

We are inviting 6 - 8 mental health workers who who will be in contact with UPSIDES peer support workers and service users in [Name of institution or catchment area] to participate in one of two groups, one before and one after the intervention.

Questions to elucidate understanding: "Do you know why we are asking you to take part in this study?" "Do you know what the study is about?"

Voluntary Participation

Your participation in this research is entirely voluntary. You can withdraw your consent to participate at any time without having to give any reasons. Withdrawal of consent will not result in any loss of benefits. There will be no effects of withdrawal whatsoever on your further medial care. You may change your mind later and stop participating even if you agreed earlier.

Questions to elucidate understanding: "If you decide not to take part in this research study, do you know what your options are?" "Do you know that you do not have to take part in this research study, if you do not wish to?" "Do you have any questions?"

Procedures and Protocol
Participation in this study means that you will be asked to meet with 5-7 colleagues who are also mental health workers to for two group interviews (also called focus group) before and after the period when UPSIDES peer support is provided. The focus groups will last for about one and a half hours each. The interviews will be recorded and will be put down in writing with anonymization of any identifying information about you or named third parties. In addition, you will be asked to complete a short questionnaire inquiring about your attitudes towards people with mental illness following working with peer support workers.

Risks and benefits of study participation
If you decide to participate, your study participation means that you will be interviewed twice for about one hour by an UPSIDES research worker together with other with other mental health workers workers. Such an interview may place a burden on some participants.

Question to elucidate understanding: "Do you have any other questions?" "Do you want me to go through the procedures again?"

Reimbursements
You will receive [insert number and currency] for study participation ([insert number and currency] for each completed assessment). Furthermore, your expenses for travelling to the research centre and back home for study participation will be reimbursed as per site-based policies.

Insurance
You will be insured for accidents for travelling to the research centre and back home for study participation based on site-based requirements [specify requirements as needed].

Confidentiality
Your data will be stored safely at the study centre for the entire duration of the study. Data transfer via internet will be encrypted using the highest standards. Only research staff and representatives of the local ethics committee will have access to individual study data. All people with access to the data are bound to professional discretion. Confidentiality of records will be maintained by assigning an ID to each participant. There will be only one list where participant ID data is stored together with the participant's name and address. This file will be stored safely and kept separate from the data used for analyses. Any personal information that could identify you will be removed or changed before files are shared with other researchers or results are made public. You are entitled to access your personal data and ask questions about them at the study centre at any time, provided a research worker is there to show you how to do that and give answers to your questions.

Sharing the results
The knowledge that we get from doing this research will be published in order that other interested people may learn from our research. You may get information about the results at www.upsides.org. You may contact the study centre at any time and ask questions about the results from this research.

Right to refuse or withdraw
I would like to make clear to you again that your participation in UPSIDES RCT is voluntary. You can withdraw your consent to participate at any time without having to give any reasons. Withdrawal of consent will not result in any loss of benefits. There will be no effects of withdrawal whatsoever on your further medial care.

Who to contact
During the time of your study participation and beyond you can contact the research centre at any time in case of any questions. Your contact person at [insert institution] will be [insert name], to be

reached via phone [insert phone number] or e-mail [insert e-mail-address]. This is also the person who you can tell that you do not want to take part in this study.

This proposal has been reviewed and approved by [name of the local IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [name, address, telephone number])

Questions to elucidate understanding: "Do you know that you do not have to take part in this study if you do not wish to?" "You can say No if you wish to?" "Do you know that you can ask me questions later, if you wish to?" "Do you know that I have given the contact details of the person who can give you more information about the study?"

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

5.2. PART II: Certificate of consent

I have read the foregoing information, or it has been read to me by [insert name of research worker]. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print name of participant _____

Signature of participant _____

Date _____
Day/month/year

If illiterate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ **AND** **Thumb print of participant**

Signature of witness _____

Date _____
Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

The participant will participate for about one hour in two focus group interviews before and after the intervention about his or her experiences with UPSIDES peer support.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant.

Print Name of Researcher/person taking the consent _____

Signature of Researcher /person taking the consent _____

Date _____
Day/month/year

6. Qualitative data to be collected from key informants

(covering section 3.2.4 of the study protocol).

[INSTITUTIONAL LETTERHEAD]

This informed consent for is for key informants who have specific authorities and/or responsibilities with regard to the implementation of UPSIDES peer support who are invited to participate in the research project "Using Peer Support in Developing Empowering Mental Health Services: pragmatic multicentre randomised controlled trial with embedded process evaluation and cost-effectiveness analysis" (short UPSIDES RCT).

[Name of Principal Investigator]
[Name of Organisation]

This Informed Consent Form has two parts:

- Information Sheet (to share information about the research with you)
- Certificate of Consent (for signatures if you agree to take part)

You will be given a copy of the full Informed Consent Form.

6.1. PART I: Information Sheet

Introduction

I am a researcher from [Name of Organisation] doing research on mental illness and how to improve mental health care. Thank you for taking your time to let us inform you about the UPSIDES project about peer support for people with severe mental illness. I will now further explain to what the project is about and I would like to invite you to participate. First of all I would like to point out that you do not need to decide right away whether or not you will participate in the study. Before you decide, you can talk to anyone you feel comfortable with about the research. This study information form may contain words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me or of another researcher.

Purpose of the research

A large number of people with severe mental illness do not receive any treatment. This has severe effects on the people affected themselves and our society in total. Peer support may be a possibility to reduce the negative effects. Here, a person in recovery from mental illness offers support to other people with mental illness. A peer support worker acts as a mentor and promotes the service users's journey towards recovery. We want to evaluate stakeholders' views on barriers and facilitators for successful implementation of peer support in the given institution, and the need for changes to make the intervention work effectively in a specific context

Type of Research Intervention

This study assesses peer support, i.e. support given by a person with lived experience of mental illness who has received training in UPSIDES peer support to a person with mental illness.

Participant selection

We are inviting 4 - 6 key informants in [Name of institution or catchment area] to participate in two interviews each, one before and one after the intervention.

Questions to elucidate understanding: "Do you know why we are asking you to take part in this study?" "Do you know what the study is about?"

Voluntary Participation

Your participation in this research is entirely voluntary. You can withdraw your consent to participate at any time without having to give any reasons. Withdrawal of consent will not result in any loss of benefits. There will be no effects of withdrawal whatsoever on your further medial care. You may change your mind later and stop participating even if you agreed earlier.

Questions to elucidate understanding: "If you decide not to take part in this research study, do you know what your options are?" "Do you know that you do not have to take part in this research study, if you do not wish to?" "Do you have any questions?"

Procedures and Protocol
Participation in this study means that you will be asked to meet with an UPSIDES research worker for an interview before and after the implementation of UPSIDES peer support. The interview will last for about one hour. The interview will be recorded and will be put down in writing with anonymization of any identifying information about you or named third parties.

Risks and benefits of study participation
If you decide to participate, your study participation means that you will be interviewed twice for about one hour by an UPSIDES research worker together with other key informants. Such an interview may place a burden on some participants.

Question to elucidate understanding: "Do you have any other questions?" "Do you want me to go through the procedures again?"

Reimbursements
You will receive [insert number and currency] for study participation ([insert number and currency] for each completed assessment). Furthermore, your expenses for travelling to the research centre and back home for study participation will be reimbursed as per site-based policies.

Insurance
You will be insured for accidents for travelling to the research centre and back home for study participation based on site-based requirements [specify requirements as needed].

Confidentiality
Your data will be stored safely at the study centre for the entire duration of the study. Data transfer via internet will be encrypted using the highest standards. Only research staff and representatives of the local ethics committee will have access to individual study data. All people with access to the data are bound to professional discretion. Confidentiality of records will be maintained by assigning an ID to each participant. There will be only one list where participant ID data is stored together with the participant's name and address. This file will be stored safely and kept separate from the data used for analyses. Any personal information that could identify you will be removed or changed before files are shared with other researchers or results are made public. You are entitled to access your personal data and ask questions about them at the study centre at any time, provided a research worker is there to show you how to do that and give answers to your questions.

Sharing the results
The knowledge that we get from doing this research will be published in order that other interested people may learn from our research. You may get information about the results at www.upsides.org. You may contact the study centre at any time and ask questions about the results from this research.

Right to refuse or withdraw
I would like to make clear to you again that your participation in UPSIDES RCT is voluntary. You can withdraw your consent to participate at any time without having to give any reasons. Withdrawal of consent will not result in any loss of benefits. There will be no effects of withdrawal whatsoever on your further medial care.

Who to contact
During the time of your study participation and beyond you can contact the research centre at any time in case of any questions. Your contact person at [insert institution] will be [insert name], to be reached via phone [insert phone number] or e-mail [insert e-mail-address]. This is also the person who you can tell that you do not want to take part in this study.

This proposal has been reviewed and approved by [name of the local IRB], which is a

committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [name, address, telephone number])

Questions to elucidate understanding: "Do you know that you do not have to take part in this study if you do not wish to?" "You can say No if you wish to?" "Do you know that you can ask me questions later, if you wish to?" "Do you know that I have given the contact details of the person who can give you more information about the study?"

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

6.2. PART II: Certificate of consent

I have read the foregoing information, or it has been read to me by [insert name of research worker]. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print name of participant _____

Signature of participant _____

Date _____
Day/month/year

If illiterate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ **AND** **Thumb print of participant**

Signature of witness _____

Date _____
Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

The participant will participate for about one hour each in two interviews interviews before and after the intervention about his or her views of implementing UPSIDES peer support.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant.

Print Name of Researcher/person taking the consent _____

Signature of Researcher /person taking the consent _____

Date _____
Day/month/year