MANCHESTER 1824

The University of Manchester

COVER Study Protocol

Full Study Title: Feasibility and Acceptability of Medical Skin Camouflage for Recovery of Women with Self-Harm Scarring in Prison: Phase 3 & 4

Research Team:

Professor Kathryn Abel: Principal Investigator

Dr Kerry Gutridge: Project Manager

Mr Brendan Dunlop: Research Assistant

Rachel Meacock: Health Economics

Professor Matt Sutton: Supervision of Rachel Meacock

Professor Christopher Roberts: Statistics

Professor Jennifer Shaw: Advice on prison research

Dr Louise Robinson: Advice on prison research

Dr Sandeep Ranote: Advice on skin camouflage for self-harm

Dr Tammi Walker: Qualitative research

Mark Craven: Local collaborator in the prison

Sponsor:

University of Manchester

Summary:

Women prisoners (WPs) comprise 5% of the prison population but are far more likely to commit suicide or self-harm (SH) than women in the community or male prisoners. Healthcare services have significantly improved the management of acute SH crises in the community and prison service but there has been little focus on the recovery, psychosocial functioning and quality of life for those living with SH scarring. Medical skin camouflage (MSC) clinics treat individuals with disfiguring conditions like burn scars and show evidence of improved recovery and psychosocial wellbeing. There is little/no evidence about MSC interventions with SH scarring or prisoners in the UK.

AIM: To test feasibility and acceptability to women prisoners with SH scarring of delivering MSC in a women's prison.

METHODS:

A separate ethics application was completed for Phase 1 and 2. These initial stages have been completed.

Phase 1: 2 stakeholder focus groups were run to explore practical aspects of delivering the medical-skin camouflage in a women's prison and to inform the choice of outcome measures. One focus group involved prison staff; the outcomes of this group focussed on practical aspects of delivering the intervention and standard operating procedures for protecting participants. The other focus group involved women prisoners with experience of self-harm; this group helped us to develop a set of women-centred, research-focussed outcome measures and explored the involvement of long-term prisoners as MSC practitioners. Women prisoners also discussed how they could be protected during the research in terms of confidentiality, bullying and abuse.

Phase 2: The findings from the 2 focus group were used to develop the procedure for phase 3 and 4 of the research. Focus group discussion enabled us to determine where, when and how treatment would be delivered, how the women and researchers should be protected during the research and which important outcomes to measure. In phase 2 we developed a training manual for the long term prisoners and an appointment checklist to ensure that they could remember the key learning points regarding MSC application when they train the participants in phase 4. To ensure that the long-term prisoners remember the aspects of the training which address confidentiality and protection of themselves and other women, we developed a summary card of the main points from this part of the training. We also developed a monitoring sheet for the long-term prisoners so they can record any questions or difficulties they have when they are training women to discuss with researchers at the weekly debriefing. Following feedback from the staff group, we also developed a list of do's and don'ts for the women in phase 4 so they can easily see how to comply with the research procedures. On the suggestion of the staff, and with an enthusiastic response from the women, we developed a diary for women to record their thoughts and actions regarding self-harm during the research period. The women's focus group also informed the development of the interview schedules and topic guide for the phase 4 qualitative research and the revisions of the scales to be used at baseline and follow up. Discussion with prison staff regarding access to medical skin camouflage also lead to the development of a GP referral letter which was modelled on a template letter successfully used in the community.

This application is for phase 3 and 4 of the project.

Phase 3. Research staff will train 6 long-term prisoners to provide MSC. The project manager has received training in MSC and has been trained to provide training to other people. She has trained the Research Assistant (RA) and will train any Clinical Support Officers (CSOs) who are involved in the research.

Phase 4. Evaluates feasibility/acceptability of prison-delivered medical skin camouflage with 40 women prisoners: 20 will be randomised to the 6-week intervention; 20 women prisoners will be wait-list controls and receive the intervention after study completion. Pre and post-intervention, we shall pilot collection of:

1. Women, service and research-centred outcomes from Phase I which include scales measuring psychosocial well-being, social functioning and everyday activities.
2. A diary of be completed during the 6-week study period which measures self-harm thoughts and actions, life events and, for the intervention group, the use of the medical skin camouflage.
3. The collection of data on resource use using proformas for staff to collect information from the different prison databases, e.g. NOMIS
4. 3-month follow-up data collection.
5. Data on recruitment, participation, retention and causes of drop-out.

Justification for the proposed research:

The aim of the study is to establish the feasibility and acceptability of medical skin camouflage for women with self-harm scarring in prison. Self-harm is a non-fatal act where an individual deliberately initiates behaviour (such as self-cutting), or ingests a substance or object intending to harm themselves (1). Rates of self-harm (incl. suicide) in England & Wales are amongst the highest in Europe (400/100,000 population/year) and have been rising over the last decade (2). Women comprise only 5% of the prison population but are responsible for the majority of prison self-harm and significantly more than comparably-aged women in the community (3-5) or male prisoners (6). Healthcare services have significantly improved their management of self-harm crises in the community and prison service (7) but there has been little focus on recovery, including psychosocial functioning and quality of life following self-harm.

Dealing with the effects of disfigurement (8) from self-harm scarring is largely unaddressed; currently a paucity of literature exists on recovery and psychological effects on individuals. In the UK, more than 390,000 individuals live with disfigurement from various non-self-harm causes which is psychologically challenging for adults trying to recover (9). Individuals with non-self-harm disfigurement struggle to cope with scarring and other pathology (10). They often face psychosocial difficulties adjusting to scarring (11) and its attendant stigma with negative outcomes for self-esteem, self-confidence, interpersonal relationships and ultimately recovery (12). Social situations may also exacerbate psychological difficulties provoking individuals with non-self-harm scarring to isolate themselves, feeling excluded from social groups and society (13, 14). Furthermore, living with scars can be challenging in a society which values physical perfection/attractiveness highly (15, 16).

Medical skin camouflage provides an essential resource for people with disfigurement from scarring, with the potential to restore self-esteem, confidence and therefore aid recovery (17-19). Medical skin camouflage uses BNF-listed preparations to disguise scars with the intention of normalising the appearance of the skin (20). The products include cover creams, liquids and powders that are waterproof, opaque and allow adherence to textured skin, including scarred areas. Each individual has a 'bespoke cream colour' and all the required products are available on NHS prescription at the discretion of the individual doctor (due to their status as borderline products). Only a handful of studies have evaluated the emotional/psychological benefits of medical skin camouflage. These have all been in dermatological diseases or burns scarring. They report significant psychological benefit, improved social and sexual relationships and the ability to secure employment (21-23). Despite this, few services offer medical skin camouflage for self-harm scarring (24). The current study has the added value that one of the co-applicants runs a new medical skin camouflage Service in partnership with Changing Faces – a registered charity, using volunteers to teach the medical skin camouflage techniques to people with mental health problems in the community. Preliminary findings from this innovative work indicate positive feedback from mental health service users with increased well-being, confidence and ability to partake in social activities.

In spite of the fact that self-harm is a considerable problem in prisons, there has been little focus on recovery or the use of medical skin camouflage in this setting. The project team has received feedback from individual medical skin camouflage practitioners who have used medical skin camouflage in HMP Holloway and HMP Eastwood Park. They report that the majority of women prisoners experience improved self-esteem and confidence as a result of using medical skin camouflage. However, no formal evaluation of outcomes related to recovery or improvement in

psychosocial functioning has been undertaken following use of medical skin camouflage in a prison environment and there are no published studies. In the phase 1 focus groups the women prisoners were enthusiastic about the products and said that they had the potential to improve their self-esteem, relationships with others and participating in activities such as going to the gym.

There are many potential benefits of promoting a recovery model of care: First, increased self-esteem, confidence and overall quality of life for women prisoners; secondly, empowering women prisoners to take part in work and social activities which they might otherwise avoid; thirdly, prison staff currently have a limited portfolio with which to work with self-harm. Our previous work has shown that there is a difficult relationship between prisoners who self-harm and staff caring for them. Staff felt restricted in how to help women or manage self-harm. This intervention may empower staff to support a pathway of recovery for women with self-harm scarring and may promote positive attitudes about self-harm in the prison and its management amongst staff.

There is limited evidence for the application and use of medical skin camouflage with women prisoners. Increasing the evidence-base using a women-and service-centred approach will help to develop medical skin camouflage so that a recovery model can be delivered to female services users in other settings such as secure services where self-harm management is also a significant problem. The main benefits of this study will be an increase in self-esteem, quality of life and recovery for women prisoners with self-harm scarring. We anticipate improving recovery provision may also importantly decrease the likelihood of repeated self-harm behaviour. It is also likely that an intervention reducing self-harm will save costs to prisons and NHS as users will use less staff time and less treatment costs in prison and on release as NHS service users. Women prisoners may become empowered to participate in work and social activities. Prison staff will benefit if a clinical intervention is more likely to encourage a recovery model of care, reduce management difficulties for staff and promote positive attitudes about self-harm. In turn, if women can develop self-management skills for their self- harm in this way, it may promote better relationships between staff and self-harming women, may reduce relapse rates and, in the long-term, promote better care pathways.

The research project will use a peer support model where long-term women prisoners will train the participants to use the MSC. Current peer support in prisons includes Listeners schemes, Insiders, Peer Advisors and Health Trainers (25). Established peer support schemes rely upon confidentiality in prisons and have been well received. A recent systematic review (26) found that ‘peer support

services are acceptable within the prison environment and have a positive effect on recipients, practically and emotionally' and that 'consistent evidence from many, predominantly qualitative, studies, suggested that being a peer deliverer was also associated with positive effects'.

Aims and Objectives:

Primary Aim: To test feasibility and acceptability of medical skin camouflage for self-harm scarring in women prisoners.

Objectives: To test the feasibility of long term prisoners delivering the modified skin camouflage intervention in a local women's prison with a sample of prisoners with self-harm scarring. To test the feasibility of the women completing the baseline and outcome measures and a diary of their self-harm experiences during the research study. To evaluate acceptability of medical skin camouflage for women prisoners. To pilot collection of 3-month follow-up data from the women. To test the feasibility of collecting resource use data for the intervention using staff-completed proformas.

Research questions: Is it feasible for long term prisoners to deliver medical skin camouflage to fellow prisoners with self-harm scarring in the prison environment? What are the barriers to recruitment, participation, retention of women? Is skin camouflage acceptable to recipients and stakeholders in prison settings? What women, service and research-centred outcomes should be adopted in a future Randomised Control Trial?

Experimental Design and Methods:

Research Design: Randomised, wait-list control.

The feasibility pilot has four phases. Phase 1 and 2 were initially submitted and given ethical approval from North East – York REC REF: 16/NE/0030. Phase 1 and 2 have been completed and have informed the development of materials and conduct of phase 3 and 4. This application is for phase 3 and 4.

Phase 1: Focus Groups (completed)

Two focus groups were run in the prison. One with staff and one with women prisoners who had self-harmed. Following analysis, a second meeting was arranged with a smaller group of women prisoners to ask follow up questions which emerged from the analysis. The aim of the groups was to

establish the practicalities of using MSC in a women's prisons, to discuss the outcome measures and any changes which would indicate an improvement in a woman's well-being following MSC use, and to establish the women's perspectives on the use of MSC in prison.

Phase 2: Adaptation of MSC intervention (completed)

Utilising the findings from Phase 1, we adapted the MSC for prison use. This involved developing a training manual and accompanying documents for the lifers and women participants, a procedure for consent and withdrawal from the research, and a process for women to access, store and use the MSC during the research. Standard operating procedures were also developed in collaboration with the prison for monitoring and managing incidents of self-harm which occur during the intervention phase.

This application is for the final 2 stages of the research – Phase 3 and 4. For Phase 3 and 4 of the study the researchers will be escorted within the prison by Mark Craven or another prison staff member.

Phase 3: 3-monthly, rolling programme of training and supporting 6 or more long-term women prisoners to deliver the intervention. Training materials for the long-term prisoners were developed in consultation with a service user researcher and women prisoners. We also consulted with Karina Lovell at the University of Manchester, who ran the Equip study which developed bespoke materials for training service users.

Aim

Test feasibility of training and supporting long term women prisoners to deliver the modified skin camouflage intervention to women prisoners with self-harm scarring.

Methods

Training sessions for long-term women prisoners will be run by members of the research team. Changing Faces have trained the project manager so she can train other people. Changing Faces is a third-sector organisation that trains volunteers to become MSC Practitioners. The project manager has trained the research assistant so she can also train the long-term prisoners. If clinical studies officers are also involved in the training they will be trained by the project manager. The training sessions for long-term prisoners will take place in a room in Safer Custody and a member of safer

custody staff will be present during all training sessions. The training sessions will take place during the core day and are considered by the prison to be purposeful activity, meaning that long-term prisoners will be allowed out of work to attend the training but will not lose out on any income. Training will be delivered following the exercises laid out in the Skin Camouflage Training Manual. Following the training the long-term prisoners will pass a record card to Mark Craven who will give the card to a nurse prescriber from the prison healthcare. The nurse will meet with the women and write a prescription for the MSC. Prescriptions will be ordered specifically for the research and will be invoiced to the research team. The prescriptions will take approximately 1 day and the nurse will alert the research team when the products are available. The research team will keep copies of the record card in case they need to provide the products, purchases online, to prisoners who have left the prison.

All materials used in the training and phase 4, below, have been pre-approved by security at the prison to ensure that the women do not have access to materials which could be dangerous for themselves or others. For example, the research team will use plastic non-breakable mirrors approved by the prison so women who self-harm will not have access to glass. Access to the MSC products is not problematic as women already have access to regular make-up and brushes.

Recruitment of long-term prisoners

Women prisoners in the phase 1 focus groups informed us that they would feel most comfortable with other prisoners with experience of self-harm delivering the MSC intervention. They said that peer delivery was preferable to delivery by staff. The research team will therefore aim to recruit at least 6 long-term prisoners with experience of self-harm to deliver MSC. Consultation with prison staff suggested that we would not find it problematic to recruit this number of long-term prisoners with experience of self-harm. Prison staff informed us that these women are also likely to be orderlies in the prison or involved in listener's schemes and assured us that these women are respected by peers and support other women already. This was also discussed by women prisoners in the phase 1 focus group; they identified and described occasions that they had been supported by long-term prisoners. Women in the focus group said they did not have concerns about trusting the long-term prisoners with confidential information. Women who volunteer to be trainers will be vetted by staff at the prison from Safer Custody and the Wings to ensure that they are safe and will not pose a risk to the women in the study and the researchers. They will be supervised by a member of the research team who will arrange weekly monitoring visits to ensure that the training is being delivered correctly and that the women are happy with their role.

We will advertise for long-term prisoners (10 years or more left on their sentence) with experience of self-harm. Advertisement will be done via monthly Queensland meetings which involve representatives from each of the wings and houses. At these meetings we will distribute leaflets and posters advertising the research. Interested women will contact Mark Craven, the local collaborator, to express an interest in the research. Following vetting the long-term prisoners will be provide with an information sheet and offered the opportunity for the research team to visit and read through the sheet with them. Consent for the research will be agreed at least 24 hours after the information sheet has been read. The consent form will additionally ask for contact details of participants (email address/telephone number) for the research team to contact them, if they are released before their participation in the study ends. The consent form will also seek permission for the research team to contact the CRC/Probation service, should the details that the participant provide no longer be valid.

Due to the prison reform and closure of Holloway women's prison there is a large amount of movement in the women's estate. The prison informed us that due to this they will be unable to put transfer holds on prisoners. We will be alerted by the prison if one of the long-term prisoners involved in the study is going to be moved. We will ensure that we train sufficient women to deliver the MSC; if we lose women to transfers we can recruit and train more if necessary. If we encounter difficulties with retention of long-term prisoners to deliver the MSC we can also train members of safer custody and the chaplaincy, but in the first instance we will train long-term prisoners as women with experience of self-harm had a strong preference for other prisoners with self-harm to deliver the intervention.

The long-term prisoners will not be able to participate in the trial at the same time as their involvement as a skin camouflage practitioner, as their involvement in this capacity might confound the results. However, if they would like to use the skin camouflage make-up they will be provided with one prescription after the research has finished.

Content of the training

The training for long-term prisoners will have 3 sections; self-harm and working with women who self-harm, safeguarding participants (including training in confidentiality) and skin camouflage training. The training materials have been discussed with a service user research with experience of being in prison and self-harm in prison, prison staff and women prisoners with experience of self-harm. The confidentiality section of the training will involve example cases which have been

informed by discussions with our service user researcher, the phase 1 focus groups, consultation with Louise Robinson, a forensic psychiatrist and consultation with Karina Lovell at the University of Manchester, who ran the Equip study which developed bespoke materials for training service users.

The training materials come with an information pack containing the following:

1. A record of the key learning points regarding working with vulnerable women and protecting themselves during the research
2. An appointment checklist for the long-term prisoners which they can take to their appointments with the women as a reminder of the key steps in the MSC process
3. A record card to be passed Mark Craven at the end of the long-term prisoner's appointment with the research participant
4. A 'do's and don'ts list to be given to the participants to remind them how to use the MSC during the research project
5. A monitoring sheet, to be completed weekly and discussed with the researchers during supervision

Support for long-term prisoners

After the training the research team will provide regular weekly supervision for practical aspects of the product use and to check that the long-term women are comfortable delivering the training. If at any point during the study the long-term prisoners experience any emotional distress or find it triggering to teach other women to use the skin camouflage creams they will inform the research team or the local collaborator, Mark Craven, who will arrange the appropriate support within the prison. Long-term prisoners will be encouraged to report any accidental breaches of confidentiality following their sessions with the women so that the researchers can liaise with the prison to ensure that the women participants are protected from harm.

Phase 3 Inclusion Criteria: Long term women prisoners. Women will have a long time left on their sentence e.g. 10 years or more. Following discussion with women prisoners in the phase one focus groups, we have agreed that the women will have personal experience of self-harm. The women will have passed the security vetting check which will be carried out by Safer Custody in association with prison officers to ensure that the researchers and participants are safe during the project. The women are likely to be people who already hold a position of responsibility in the prison e.g. Samaritan listeners or orderlies.

All participants will be aged 18 or older and able to give written, informed consent. Capacity to consent will be assessed by the experienced researchers. If capacity is in doubt the researchers will discuss individual participants with Safer Custody and Mental Health Care contacts in the prison, Mark Craven and Suzanne Cook.

Phase 3 Exclusion Criteria: Women will be excluded if they have insufficient time left on their sentence, are deemed too high risk to others, are unable to give informed consent or have no direct experience of self-harm.

Phase 4: Delivery of MSC and Evaluation of its Acceptability

Quantitative aims: recruit and randomise 40 women to MSC for 6weeks or wait-list control (to receive MSC after the research has ended). Pilot the following:

1. Women, service and research-centred outcomes from Phase I which include scales measuring psychosocial well-being, social functioning and everyday activities
2. A diary to be completed during the 6-week study period which measures self-harm thoughts and actions, life events and, for the intervention group, the use of the medical skin camouflage.
3. The collection of data on resource use using proformas for staff to collect information from the different prison databases, e.g. NOMIS
4. Follow-up data collection, 3 months after the post intervention assessments.
5. Data on recruitment, participation, retention and causes of drop-out.

Qualitative aims: acceptability of MSC for stakeholders and the acceptability of training long term women prisoners to deliver the MSC training to participants

Recruitment & Participants

The advertisement strategies were informed by consultation with prison staff and women prisoners in phase 1. Prison staff suggested that we present the research at monthly Queensland meetings which involve representatives from all of the houses. We will also go in the evening to Bollingwood, the open house outside of the main prison gate, to discuss the project with women who are on open house. We will distribute leaflets and posters at the Queensland meetings and these will then be displayed around the prison. We will also run a drop-in showcase and awareness session for ½ day each week which will take place in safer custody, with a member of safer custody staff present. This

will enable women to find out more about the trial and ask us questions about participation. Women will inform our local collaborator, the head of safer custody, Mark Craven, if they are interested in taking part in the research. The women who volunteer will be vetted by staff at the prison from Safer Custody and the Wings to ensure that they are safe and will not pose a risk to the researchers. Following vetting the women will be provided with an information sheet and offered the opportunity for the research team to visit and read through the sheet with them. Consent for the research will be agreed at least 24 hours after the information sheet has been read.

Prison staff informed us that we may identify some women who they do not know are self-harmers e.g. women who self-harm on their legs or torso. We will ensure in the meetings and showcase events that women know that by expressing their interest the prison will be aware of this and will know that they self-harm.

If a woman is excluded by the prison on the grounds of safety a member of the safer custody team will speak to them to inform them that they will be unable to participate in the research. The safer custody team are experienced in working with women who self-harm and supporting women in the prison. They will be able to deal with this sensitively and arrange the appropriate support for the woman if anything is required.

The sample size is 40 women prisoners overall. In the prison, there are ~40 active self-harming women prisoners per month (Nov 2013), of whom 25 have closed wounds, and 15-20 are likely to be eligible for camouflage per month. Our two recent consultations with stakeholders in the prison and the phase 1 focus group suggest interest in the intervention is high among women prisoners. 20 women prisoners will be randomised to receive the 6-week intervention; the other 20 women prisoners will be wait-list controls and receive the intervention after study completion. In the focus group with women we explored how they would feel about being randomly allocated to intervention or wait-list control and the women said they would not mind as they would still get to use the products after the research. As piloted in WORSHIP II, we shall censor women by release-date to reduce attrition, and try to follow the few women moved before the end of 6-weeks. If a woman has left prison before the three-month follow-up we will ask the prison to send the follow up letter to the women in the community. The women will have consented to this approach at the start of the research. Follow up in the community will involve completion of the questionnaires via distance methods e.g. email, post or telephone interviews. If a wait-list control woman leaves the prison

before the MSC is provided they will be instructed to contact the research team and will be posted their bespoke skin matched creams and powders.

Phase 4 Inclusion Criteria: Remand and sentenced women prisoners screened for date of release, with at least 6 weeks left on their sentence. The women will have passed the security vetting check which will be carried out by Safer Custody in association with prison officers to ensure that the researchers are safe during the project. The women will have self-harm scarring, with some closed wounds (to allow the MSC to be applied).

All participants will be aged 18 or older and able to give written, informed consent. Consent forms will detail that participants consent to be followed up in the community if they have been released, and are happy to provide the research team with contact details of their choosing (email address/phone number) to facilitate this follow-up. Capacity to consent will be assessed by the experienced researchers. If capacity is in doubt the researchers will discuss individual participants with Safer Custody and Mental Health Care contacts in the prison, Mark Craven and Suzanne Cook.

Phase 4 Exclusion Criteria: Women prisoners will be excluded if they only have open wounds, have less than 6 weeks on anticipated release date, are deemed too high risk to others, are not able to give informed consent to participate or have allergies to perfume and lanolin.

Outcome Measures

The baseline assessment will take place in safer custody with a member of the research team or a CSO. We have an agreement with the Clinical Research Network that there are CSOs who will be able to assist with data collection. The assessment will last around 1 hour. If, at any point during the assessment the woman becomes agitated or distressed, researcher will ask them if they would like to take a break or if they would like to complete the rest of the measures on another day. If the researcher has any concerns for the woman they will ask permission to alert Mark Craven who will ensure it is dealt with accordingly using the existing prison support systems.

We will pilot the collection of a set of women, service and research-centred outcomes which were informed by Phase 1 focus groups:

At baseline assessment we will work through the following scales with the women: DSHI, BSSI, BHS, BDI, EQ5D, SF12, WEMWBS, Rosenburg Self-esteem scale, DLQi, Zanarini PD Scale. See below for full

descriptions of the measures. The DLQi and Rosenberg Self-esteem Scale were added following focus group discussions on the psychological and interpersonal impact of scars and the effects on a woman's self-esteem.

With women's permission, we will also access information on key clinical characteristics from CNomis, SystemOne (the prison electronic medical records) and from ACCT documentation. These systems will be accessed by prison staff unless the researchers are given permission to access them. Consent to access the systems and extract information will be sought for all women. Information on relevant personal history including past psychiatric history, domestic violence, sexual abuse and parental neglect history will be collected using a bespoke demographic and personal history questionnaire which was used successfully in the WORSHIP projects. This information will be collected to check whether the two randomised groups have similar backgrounds.

During the 6-weeks skin camouflage intervention we will also ask each participant to complete a weekly diary. This idea was proposed by prison staff and women prisoners, some of who had completed a diary of self-harm thoughts and events in the past. The research team will collect the diary from the women at the end of the week. The diary will include any thoughts or acts of self-harm that have occurred during the week. It will also list any life events that have impacted on a women's self-harm. For the intervention group the diary will record their thoughts on the skin camouflage creams and powders. Women will also be able to note down any extra comments or thoughts from the week.

We will also pilot the collection of resource use data. A series of resource use pro-formas will be created for each woman. Prison staff will extract data from each of the prison systems. The pro-forma will be marked with the start date and end date (6 weeks apart) for the woman and resource use data will be extracted from Nomis, Officers logs, Business hub etc. Information on these systems will be redacted by prison staff before it can be passed on to the research team, e.g. to remove specific information about media-reported index offences. These systems will also be used to extract data on self-harm incidents which occurred during the 6-week intervention.

At post-intervention assessment. The following scales will be completed at 6 week's post-baseline and 3 months after the 6 weeks post-baseline assessment: DSHI, BSSI, BHS, BDI, EQ5D, SF12, WEMWBS, Rosenburg Self-esteem scale, DLQi, Zanarini PD Scale. Consent will be sought at baseline for women who have left prison before 3 months post-intervention to be followed up in the

community. Follow up will be via distance methods, with scale completion by email, post or over the telephone.

Treatment Details: Skin camouflage clinics will be run by the long-term prisoners who have been trained to deliver the medical skin camouflage intervention. Clinics will be held during the core prison day and will not interfere with the women's income. A member of safer custody staff will be present whilst the long-term prisoners are running the clinics. Each participant in the trial will be seen individually for one hour. During this appointment, the participant will receive information about the specially formulated MSC creams. This will include the long-term prisoner informing them about any potential allergens in the creams and ensuring the participant does not have any allergies which will prevent them from safely using the creams. Participants will also be told that the products do not include anything which would give them a high (at the recommendation of prison staff). The long-term prisoner will take the participant through the ethnic skin tone colour-matching process and will try small amounts of cream until they find a match. After this, they will apply the cream to a larger area and use special powders to set the cream and make sure it is waterproof. Throughout the appointment, an explanation of what they are doing will be given to participants and they will be able to watch the process in a plastic mirror. The participant will then be able to try applying the camouflage creams themselves. When they are happy with how it looks, the practitioner will complete a record form which will be given to Mark Craven to pass to healthcare. A nurse prescriber from healthcare will then arrange a meeting with each woman and will write her a prescription. Women will be told at the outset of the study that they will only be given the MSC for the duration of the study. The amount of camouflage cream used in each application will vary per woman depending on the extent of the scarring, but we anticipate that only one prescription will be required for the research.

Women will be given the cream and powder and will be able to keep these in their houses. Each woman has access to a safe and will have the choice of locking the products away if they wish. The research team and prison staff will make it clear to the women that the products should not be traded or shared with other women. Feedback from women prisoners in the phase 1 focus group suggested that they would not trade the make-up and therefore the likelihood of trading is deemed to be low. Members of the research team will meet with women on a weekly basis to do spot checks on the products and to collect the weekly diary. Prison staff advised that spot checks would be a good idea and are done for in possession medications so women are used to these procedures. If the

research team has any concerns about the products being shared or not used in the correct way they will discuss this issue with Mark Craven, the local collaborator.

Whilst using the products the women will be monitored, as usual, by Mark Craven and his team in safer custody. They will ensure participant safety and if any participant needs to be referred to a care team or for another form of support within the prison this will be dealt with by Mark Craven. Any events of self-harm which occur during the study period will be dealt with following ACCT procedures. Self-harm events will also be assessed to determine whether they are serious adverse events caused by participation in the research project. If so, the study has standard procedures which will be followed, as outlined in the standard operating procedures document. If a woman wishes to withdraw herself from the study she will inform Mark Craven and, with the woman's permission, he will record the reason for withdrawal. Any women who withdraw from the study will be asked if they would like to meet with a member of the research team to talk about their participation in the project and why they wished to withdraw. It will be stressed that this is completely optional.

As requested by prison healthcare staff, the research team will explain that there is no guaranteed access to the medical skin camouflage products after the research. The research team will write follow-up GP letters for all of the women in the trial which will detail their involvement in the study and list the names of the products that they were prescribed. This will help women to access the products when they return to the community.

All women in the treatment and control group will be skin matched at baseline. This will ensure that any wait list control participants who leave prison before the 3 month follow up will be able to be posted skin matched products by the research team on request.

Qualitative follow –up

(1)We shall undertake qualitative interviews examining acceptability of the intervention for participants, prison health and other prison/disciplinary staff. Approximately 20 participants who received the treatment will be invited by the team to evaluate their experience of the intervention and explore their views on treatment accessibility i.e. applying MSC, how long it stays on for, its perceived usefulness, effects on everyday life and potential impact on how women feel about their scarring, mood, self-esteem and self-confidence.

(2)Members of the research team will undertake a focus group with 6-10 prison health and other/disciplinary staff who have had direct contact with participants who received the treatment intervention. Their views will be explored in relation to the treatments' acceptability and perceived effects on participants' well-being, quality of life and everyday functioning.

(3)We shall undertake qualitative interviews examining acceptability of the training and being a practitioner in the prison. Six semi-structured interviews will be undertaken by the team to explore how acceptable the training was, how it was used with participants, mentoring/support from the research team and any benefits or difficulties working with participants.

(4) The Research Assistant will undertake four focus groups with women prisoners to explore what wellbeing means to them. This will help to inform the development of a 'wellbeing in prison' measure which could be used in future projects.

We have developed detailed interview schedules and topic guides to facilitate the qualitative elements of the study which were informed by the phase 1 focus groups.

Outcome measures:

1. Warwick-Edinburgh Mental Well-Being Scale (WEMWBS): a 14-item scale of mental well-being covering subjective well-being and psychological functioning, in which all items are worded positively and address aspects of positive mental health. The scale is scored by summing responses to each item answered on a 1 to 5 Likert scale. The minimum scale score is 14 and the maximum 70.

2. Becks Scale for Suicidal Ideation (BSSI): a 19-item instrument measuring intensity, duration and specificity of thoughts about committing suicide. The 19 items are rated on a three-point scale (0-2).

3. Becks Depression Inventory (BDI): a 21-item scale measuring symptoms of depression. Items are rated on a 4-point scale (0-3) with severity of self-reported depression: 0-9 minimal; 10-16 mild; 17-29 moderate and 30-63 severe.

4. Beck Hopelessness Scale (BHS): a 20-item self-report inventory designed to measure three major aspects of hopelessness: feelings about future, loss of motivation and expectations.

5. Deliberate Self-Harm Inventory (DSHI): a 17-item questionnaire giving history and frequency of self-harming behaviours.

6. Prison-adapted Dermatology Quality of Life Index (DLQi): a 7-item questionnaire adapted from a validated 10 item scale that has been used in over 40 different skin conditions in over 80 countries. The DLQi is the most frequently used instrument in studies of randomised controlled trials in dermatology.

7. Rosenberg Self-Esteem Scale: a 10-item Likert scale with items answered on a four-point scale – from strongly agree to strongly disagree. The scale measures self-esteem and has been used in prison research.

6. Incidence and frequency of self-harm will be collected from participant's prison records and the weekly diary.

7. We shall explore acceptability/relevance of two generic preference-based health-related quality of life (HRQoL) measures: The EQ-5D-5L covers five domains of health (mobility, self-care, usual activities, pain/discomfort, anxiety/depression). This new version was developed due to concerns over the lack of sensitivity to change of the original EQ-5D-3L, and consists of five severity levels for each domain (no, slight, moderate, severe, and extreme problems) rather than the original three levels (no, moderate, or extreme problems). Participants' responses are converted to a single index utility value based upon preference weights obtained from a UK general population sample.

SF-12 is a shortened version of the SF-35, consisting of twelve questions covering eight dimensions of health: physical functioning, role limitations - physical, bodily pain, general health, vitality, social functioning, role limitations - emotional, and mental health. A single index utility value is then obtained by applying published SF- 6D preference weights.

8. Members of the prison staff will complete resource use proformas (based on the Secure Facilities Service sue Schedule) for all participants and the research team will record including time spent by Changing Faces training the researchers, time spent by trained prisoners delivering the intervention, and quantities of MSC products used and prescribed. Descriptive analysis will inform future trial design.

9. Demographic and relevant personal history will be collected using a bespoke personal history questionnaire, previously used in a prison population in the WORSHIP projects.

As per HMPPS rules and regulations, no incentives or payments can be offered to participants whilst they are residing in the prison. However, the research team will provide an incentive for released women to complete follow-up outcome measures in the community. This will take the form of a £20 gift voucher, as well as reimbursement of travel expenses. This voucher will be given to compensate for their time and effort in coming to the appointment.

Analyses

(1) Feasibility and Acceptability: primarily qualitative (Phases I /4), but includes quantitative assessment of treatment attrition. Verbatim-transcription analysed using thematic content analysis.

(2) Quantitative data: Insufficient power for quantitative hypothesis testing means before and after treatment changes are descriptive including standard deviations and confidence intervals for outcome variables to inform sample size estimates for future RCT and assessment of feasibility of control group retention.
(3) Feasibility of delivering and acceptability and relevance to the prison population of EQ-5D-5L, SF-12 will be assessed through correlation between changes from baseline to follow-up of these and other piloted measures (WEMWBS, SOS-10, PANAS, BSSI, BDI, DSHI); and examination of completion rates. Descriptive analysis of HRQoL data will also be performed to inform the suitability of the measures for future clinical and economic evaluations of MSC in prison.
The resource use proformas will be assessed through time taken to complete the forms, completion rates, and ability to obtain included resource-use categories.

Survey
We shall create, produce and conduct a short five-question paper survey, which will be offered to all prisoners within HMP Styal. This survey will ask questions related to prisoner wellbeing, and will be distributed through the prison's internal mail system. Participants will not be obligated to fill out this survey Participants wishing to fill out this survey will be provided with a participant information sheet detailing what is involved in filling out this survey, and will need to provide written informed consent (by filling out a consent form) when returning the survey**.**

Benefits of the study:
The main benefits of this study can be divided into those for the prison and those for the wider NHS/public
1. Women prisoners with self-harm scarring are likely to benefit from an increase in self-esteem, quality of life and recovery. We anticipate this will lead to greater participation in activities and rehabilitation programmes in the prison. Women in the phase 1 focus groups said that using the MSC may deter them from further self-harm and taking time to apply the make-up may enhance self-care and motivate them to live a healthier lifestyle.
2. Long-term prisoners may find it rewarding to participate in research. In addition, research suggests that peer support can also improve the wellbeing of those who provide it.
3. Our co-applicant reports preliminary data for the intervention in community self-harmers who show reduced stigma of scars from self-harm, reduced feelings of shame, decreased bullying, peer group rejection and isolation, increased engagement with peer groups, social activities.

4. Improving recovery provision in the prison environment importantly will decrease the likelihood of repeated self-harm behaviour and greater long term scarring.
5. An intervention that reduces self-harm behaviour will also be likely to produce significant efficiency savings for prisons as the cost of managing women who self-harm (diverting officer resources to their care; reducing ACCT numbers) and their treatment will be reduced.
6. Improving the portfolio with which prison staff can work with women prisoners who self-harm will improve relationships between prisoners who self-harm and staff caring for them. Staff will feel more empowered to support a pathway of recovery for women with self-harm scarring as the study will promote positive attitudes about self-harm in the prison and its management amongst staff.
7. Modifying with stakeholders the various Scales and piloting their use in prison will benefit this population by validating their use in prison research.
8. Assessing the acceptability and relevance of two generic preference-based health-related quality of life measures; the EQ-5D-5L and the SF-6D, to the prison population will inform the suitability of these measures for use in future clinical and economic evaluations in this setting.

Wider NHS/public benefits:

1. Upon release, when the women prisoners continue to be NHS service-users, women prisoners may become empowered to participate in work and social activities that they otherwise might avoid because of low self-esteem/ self-confidence and the stigma of scarring.
2. The community pilot supports this notion as it suggests positive effects are associated with improved self-esteem, confidence, personal development and activities of daily living/functioning and reduced risk of mental illness or relapse.
3. The risk in the longer term of unemployment and/or days off school/college and the economic burden associated with this in a vulnerable ex-offender population is considerable. Therefore, positive effects on this risk-burden are likely to be significant to the wider public.
4. The study will also increase the evidence-base for using a women- and service-centred approach for developing medical skin camouflage services in the NHS more broadly as well as promoting development of a recovery model to be delivered to women services-users in other settings, such as secure services where self-harm management is a highly significant problem.
5. Barriers and benefits to this recovery intervention identified in the study can be embedded in Safer Custody generic guidance (e.g. Prison Orders) through NOMS partnership working to improve healthcare delivery for self-harm recovery within women's prisons.

Data Management

The research team has permission from the prison to take two digital recorders into the prison. After each session the researchers will download the interview audio files onto computers at the University of Manchester and delete them from the digital recorder. Data will be stored in an encrypted space on the University computers. This ensures that the data is held securely in one location. Moreover, the participants will be anonymous as their names will not be recorded on any of the audio files. Written consent forms and paper completed questionnaires will be removed straight to the University of Manchester. The questionnaires will be input into computers at the University of Manchester. All data on the computers will be stored in an encrypted space. All personal data will be stored at the University of Manchester in a locked filing cabinet and personal identifiable data will be stored separately from other research data and from participants' identifying codes. In the University of Manchester this will mean storage in the locked limited access corridor.

Transcription of the audio files will be done by an approved external service that complies with data protection regulations, following advice from University data protection experts. The transcription company will provide an agreement that any audio files in their possession will be stored on an encrypted space. A formal contract will be drawn up between the University and the transcription company to ensure that the company complies with Data protection and confidentiality.

Anonymised, encrypted research data may be transferred between the research team by email. Personal data will not be transferred electronically. Audio interview recordings and transcripts will be transferred electronically to an external transcription company. All files transferred electronically will be password protected and encrypted. Published quotations will be anonymised.

The research team will be based in the Centre for Women's Mental Health at the University of Manchester and will abide by the Universities Confidentiality policy which forms part of the Information Security and Management Policy. Confidentiality clauses are included within staff contracts. All staff are aware of their responsibilities. The University policy satisfies the requirements of the Data Protection Act.

The research team will have access to participants' personal data. This includes details such as demographic data, past psychiatric history and abuse history, sentence type, data on new self-harm incidents and any related life-events and data on resource use specific to self-harm. This information is necessary to assess the impact of Medical Skin Camouflage and to ensure that the two randomised

groups are comparable. Personal data will only be collected when there is written informed consent. Stored data will be anonymised with identifying information kept separately in a locked filing cabinet. Study data and material may be looked at by individuals from the University of Manchester, from regulatory authorities or from the NHS Trust, for monitoring and audit purposes, and this may well include personal information.

Published quotations will be anonymised. We will ensure that anonymised data across publications cannot be used in combination to identify individuals.

In accordance with the guidelines of the University of Manchester the research data will be stored for at least 5 years after the last publication based on the data or for 10 years (whichever is greater).

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