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Medical skin camouflage for women in prison with self-harm scars (COVER): randomised feasibility study

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ABSTRACT

Far more women prisoners self-harm than women in the community or men in prison. There has been little focus on the effects on prisoners of living with self-harm scars. Medical skin camouflage (MSC), designed to cover skin disfigurement, improves quality of life for people in the community with dermatological, burn, surgical or accidental scars or marks. Its use in prison for self-harm scars has not been evaluated. COVER tested the feasibility and acceptability of a wait-list control RCT of peer-delivered MSC for women prisoners with self-harm scars, at one prison. We provide evidence of feasibility to recruit, randomise and retain women in prison in an RCT design using strategies minimising attrition from transfer between prisons or release (51 recruited, 11.8% attrition). We successfully randomised women prisoners and collected outcome measures over 12 weeks from baseline. We report improvements in the primary outcome, the Warwick-Edinburgh Mental Well-Being Scale at follow-up for intervention and control groups and valuable information to inform an economic analysis. Important lessons were learnt, applicable to other research within this unique environment, about minimising attrition and successfully involving prisoners in peer-delivered interventions. Participants and staff found the intervention acceptable and suggested it improves women's confidence and self-esteem.

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KEYWORDS Medical skin camouflage; women; self-harm; prison; feasibility and acceptability RCT

Introduction

Self-harm is significantly more common in prison than in the community, and this is particularly the case for women in prison compared to men (Home Office, 2007; Shaw et al., 2003). Thus, 3810 self-harm incidents were recorded per 1,000 women compared to 537 per 1,000 men in prison in the 12 months

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to June 2022 (Ministry of Justice, 2022). The exact financial cost of self-harm in prison is unknown, but likely to be considerable when we account for staff hours managing self-harm, wound treatment, hospital stays, escorts, self-harm reporting and investigation.

Effects of self-harm scars

Most research on self-harm in prisons has to this point, perhaps understandably, focussed on understanding the determinants, management, and ways to intervene. There has been little focus on the psychosocial functioning of women living with self-harm scars in prison (Gutridge et al., 2019). Previous research on dermatological or accidental skin disfigurement, in other settings, suggests that disfigurement lowers self-esteem, confidence, and negatively influences relationships and daily activities (Sreedhar, 2009). A focus group with women prisoners suggested that women who self-harm in prison were similarly embarrassed by their scars and concerned about the judgments of others (Gutridge et al., 2019). They discussed the importance of covering their scars and had used clothing, high-street make up and tattoos for this purpose to enable them to confidently participate in activities or work.

Medical skin camouflage

Medical skin camouflage (MSC) is designed to reduce the visibility of scarring or disfigurement (McMichael, 2012). The charity – 'Changing Faces'- runs community MSC clinics (Faces, 2020). Few studies have evaluated the psychological effects of MSC, and none has focused on self-harm. However, a systematic review of MSC for skin disfigurement concluded that it could result in significant improvement in quality of life (Kornhaber et al., 2018). The most common quality of life measure was the Dermatology Life Quality Index (Finlay & Khan, 1994) which assesses the impact of scarring on work, activities and personal relationships (amongst other things); all important aspects of rehabilitation.

COVER is the first study to examine MSC use by women in prison who self-harm. We aimed to test the feasibility and acceptability of a randomised controlled trial evaluating the effect of MSC on psychosocial wellbeing and the cost-effectiveness of the intervention for women in prison with self-harm scars.

In designing this study, we were aware of the challenging prison environment. Therefore, we undertook significant consultation with staff and prisoners early on. We were particularly concerned that the intervention would be sustainable. Our consultation suggested that women prisoners with self-harm scars preferred the idea of being taught to use MSC by

peers with experience of self-harm (Gutridge et al., 2019). For this reason, we designed a prisoner delivered intervention to assess the feasibility of delivering MSC to women prisoners with self-harm scars in preparation for a full future trial.

Methods

Design

The study protocol was finalised and published (Mitchell et al., 2019). Between January 2017 and June 2018 participants who used MSC for 6 weeks were compared with a wait-list control. The trial followed preparatory work (previously published (Gutridge et al., 2019)) with prison staff and women who self-harmed in prison; this was used to adapt the intervention for peer-delivery in prison. The trial assessed the feasibility of:

- recruiting and retaining participants in an RCT of MSC;
- using prisoner and peer-delivery of the intervention;
- collection of wellbeing/psychosocial outcome measures;
- collection of self-harm incidents;
- collection of resource-use data.

We evaluated the acceptability of the intervention for prisoners and staff. The protocol describes additional design details (Mitchell et al., 2019).

Measures

Demographic, clinical characteristics, and self-harm history were collected at baseline using a bespoke personal history questionnaire and the Deliberate Self-Harm Inventory (Gratz, 2001) so we could compare the two randomised groups.

We aimed to collect the following psychometric measures at baseline, 9 weeks (allowing 3 weeks for skin matches and prescribing before the intervention began) and 12 weeks from baseline:

- Warwick-Edinburgh Mental Well-Being Scale (Tennant et al., 2007)
- Beck Scale for Suicide Ideation (Beck et al., 1979)
- Beck Depression Inventory II (Beck et al., 1996)
- Beck Hopelessness Scale (Beck et al., 1974)
- Rosenberg Self-Esteem Scale (Rosenberg, 1965)
- A prison adapted version of the Dermatology Quality of Life Index (Finlay & Khan, 1994)

The trial outcome measures were reviewed for relevance by the preparatory focus group participants (Gutridge et al., 2019). We aimed to examine whether the Warwick-Edinburgh Mental Well-Being Scale (WEMWBS) would be a suitable primary outcome for a full-scale RCT (Mitchell et al., 2019).

Self-harm incidents were collected by: a weekly diary (self-completed or completed with researcher support); searches of the prison self-harm incidents log; and searches of the electronic prison healthcare record, SystmOne. We checked the date and time of incidents, across the data sources, removing duplicates to determine total self-harm incidents.

To assess the feasibility of collecting data needed for a future economic evaluation, we collected two measures of health-related quality of life, the EQ-5D-5 L (Gusi et al., 2006) and SF12 (from which we derived the SF-6D) (Brazier & Roberts, 2004) and piloted the collection of resource use information using the Secure Facilities Service Use Schedule (SFSUS) (Barrett & Byford, 2007). The SFSUS records individual-level data on service use within secure facilities and external services. Obtaining information on resource use is challenging in this setting, and cost-effectiveness studies are rarely conducted. We, therefore, assessed the availability of resource use information in two existing prison databases: SystmOne; and the prison operational database, the National Offender Management Information System (NOMIS). Resource use was collected retrospectively.

Setting

The research took place in one English, closed female prison. All research contacts were via the Safer Custody department.

Participants

The trial was advertised in posters, leaflets, and word of mouth. We also had a stall at a prison-wide event where women could approach researchers for project information.

Women aged 18+ were eligible to participate if: they had self-harm scars with at least some closed wounds for hygienic MSC application; they had capacity to consent to participation; and were remanded or sentenced prisoners with at least 9 weeks left within the prison, to allow time for follow-up. Women were ineligible if they posed a risk of harm to the researchers as assessed by prison staff. Written informed consent was obtained from the peer-practitioners and participants.

The peer-delivery model

The study evaluated an innovative, peer-practitioner model with prisoners delivering the intervention. The aim was to create an empowering and sustainable peer-delivery service. A manualised peer-practitioner method was considered to be sustainable as the practitioners would remain in the prison for at least 10 years and, with minimal additional training, staff or current peer-practitioners would be able to train their replacements. The research team ran MSC group training with 11 consenting, long-term prisoners, with at least 10 years or more left on their sentence, with personal experience of self-harm, considered safe to work in a supportive role by prison staff.

Training of the long-term prisoners took place in the Safer Custody department and was delivered by research team members. Each practitioner received 4–6 hours of training, delivered during a single session. The manual was a version of Changing Faces' MSC manual adapted for prison use in consultation with staff and prisoners to ensure that the practitioners adhered to prison security protocols and were sensitive to prisoners' needs. Changing Faces approved the adapted manual. Additional training details are available elsewhere (Mitchell et al., 2019).

The intervention

We aimed to recruit 40 women into the RCT study. 20 women would be randomised to receive the intervention for 6-weeks and the other 20 women be 'wait-list controls' and be able to receive the intervention after study completion, if they wished.

The intervention consisted of: 1) a skin camouflage appointment with a trained peer-practitioner and 2) one prescription of skin camouflage cream and powder to last 6 weeks.

Women in the intervention group received a one-to-one skin camouflage appointment with a peer-practitioner after randomisation, lasting approximately one hour. During this appointment, the practitioner provided the participant with information about the MSC products, including allergy checks for safety. They then 'colour-matched' the participants with the product and demonstrated application techniques. The participants practiced applying the MSC until they were confident with its use. Following the appointment, the peer-practitioner completed a record card which was sent to a nurse prescriber who met with participants to order their prescription.

Appointment booking and delivery of the MSC products was supported by prisoner administrators working in Safer Custody. Initially, this was one prisoner, but later two women.

Randomisation

Individual internet randomisation was completed using, Sealed Envelope.

Follow-up

Remand prisoners spend an average of 9 weeks in prison (Prison Reform Trust, 2010) and sentenced women an average of 6–8 weeks (Independent Monitoring Board, 2010). Women can be transferred to another prison or released at short notice. Therefore, we piloted strategies to ensure that we could access women for follow-up, taking these things into account.

Statistical measures/Outcome measures

As this was a feasibility trial, analyses are descriptive. A CONSORT diagram describes participant flow. Specifically, we collected data on the number of women who expressed interest, were eligible, were randomly assigned to each arm, received the intervention and provided outcome data. Baseline, 9 and 12 weeks from baseline outcomes were also collected.

To evaluate the effectiveness of randomisation, we assessed the comparability of the intervention and wait-list control groups. Fisher's Exact Test was used for categorical baseline characteristics and the Mann Whitney U Test for continuous characteristics.

Trial and intervention acceptability

To assess acceptability of the trial and intervention, post-intervention qualitative interviews were conducted with participants and the MSC peer-practitioners and a focus group with staff.

Ethics statement

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008. All procedures involving human subjects/patients were approved by West of Scotland REC 3, 16/WS/0155.

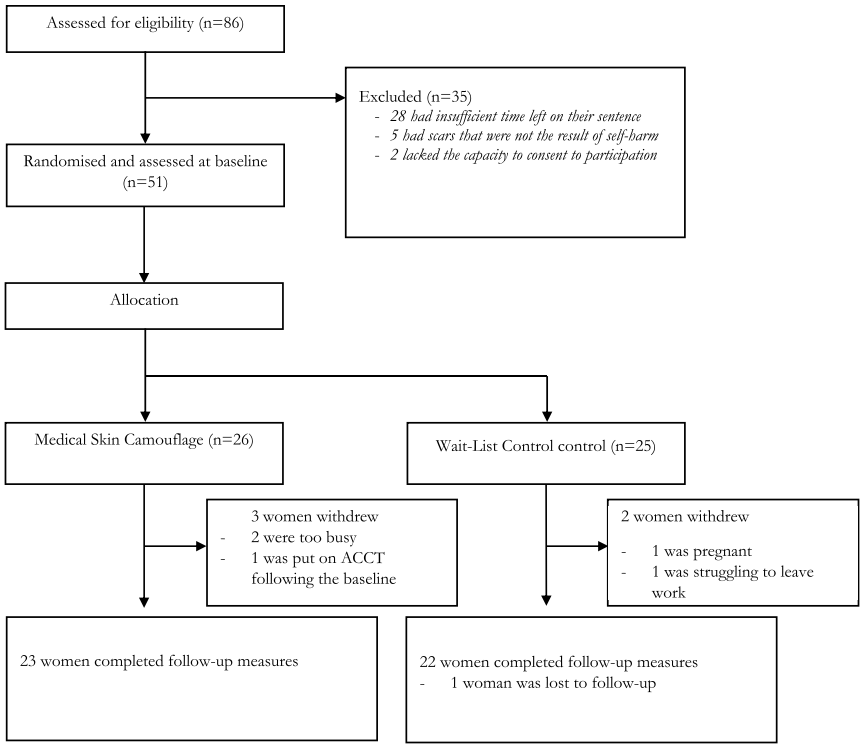

Figure 1. CONSORT flow diagram: progress of women prisoner participants through trial.

Results

Recruitment and participant flow

Of the 86 initial volunteers to receive MSC, 51 women prisoners met eligibility criteria, completed baseline assessments and were randomised to the intervention ($n = 26$) or control ($n = 25$) (Figure 1). This exceeded anticipated recruitment by 11. Of the 86 women, 28 were excluded because of insufficient time left in prison; five because their scars were not from self-harm; and two due to lack of capacity to consent (determined through discussion with Safer Custody staff).

Forty-five women completed follow-up assessments (most either 9-week or 12-week measures rather than both). Five women withdrew because they were: too busy ($n = 2$); they were unhappy about being put on the Assessment, Care in Custody and Teamwork (ACCT) process (the prison self-harm monitoring system) after the baseline assessment as a result of the research assistant reporting risk (a safeguarding measure included in the consent procedure) ($n = 1$); were pregnant and decided they did not want a long-term commitment ($n = 1$); or found it difficult to leave work to attend

appointments ($n = 1$). One participant was lost to follow-up because they left prison and probation had lost contact.

We completed qualitative interviews with 18 intervention group women, 21 women from the control group and five peer-practitioners and a focus group with nine staff.

Effectiveness of randomisation

Baseline participant characteristics are shown in Table 1. The intervention and control group had similar demographic and personal histories – other than a history of alcohol dependence, more common in the intervention group ($p = .007$); a history of parental neglect, more common in

Table 1. Baseline characteristics.

		Intervention		Wait list control		
		Frequency	Percentage	Frequency	Percentage	Fisher's Exact Test p value
Ethnicity	White	22	95.7	22	95.7	
	other ethnicities	1	4.3	1	4.3	1.000
Prison Status	Sentenced	20	87.0	23	100	.233
	Remand	3	13.0	0	0	
Previous Imprisonment	Yes	12	52.2	10	45.5	.768
	No	11	47.8	12	54.5	
Previous contact Psychiatric Services	Yes	17	73.9	20	87.0	.459
	No	6	26.1	3	13.0	
Age of onset self-harm	10 or under	3	13	8	34.8	.165
	11 or over	20	87	15	65.2	
Current or previous drug dependence	Yes	14	60.9	10	43.5	.376
	No	9	39.1	13	56.5	
Current or previous alcohol dependence	Yes	15	65.2	5	21.7	.007
	No	8	34.8	18	78.3	
Experienced sexual abuse as a child	Yes	11	47.8	15	65.2	.541
	No	10	43.5	8	34.8	
Experienced Sexual abuse as an adult	Yes	6	26.1	8	34.8	.752
	No	15	65.2	15	65.2	
Experienced domestic violence	Yes	17	73.9	20	87.0	.459
	No	5	21.7	3	13.0	
Parental Neglect	Yes	6	26.1	14	60.9	.036
	No	16	69.6	9	39.1	
		Mean Rank	Sum of Ranks	Mean Rank	Sum of Ranks	Mann Whitney Test
DSHI		22.39	515.00	24.61	566.00	.574

the control group ($p = .036$). The participants' baseline scores on Deliberate Self-Harm Inventory were not significantly different (DSHI $p = .574$).

Therefore, we conclude that randomisation was effective at ensuring similarity in key variables between the intervention and control group.

The feasibility of randomising women to the intervention or wait-list control was also assessed in terms of drop-out in the control group (two women) in comparison to the intervention group where three women dropped out. Reasons for leaving the control-group were reported as pregnancy and difficulty leaving work. Three other women expressed disappointment that they were in the control group but remained in the study, although one borrowed a friend's MSC.

Attrition

Attrition was 11.8%. Strategies aimed at minimising attrition were used throughout including: screening women for release date to ensure sufficient time remaining in prison; requesting transfer holds from Governors, with the women's consent, to reduce movement between prisons; following-up women at any women's prison; collecting multiple community contact details at baseline; seeking permission to contact women via the probation service and offering released women compensation for their time and expenses during community follow-up.

Intervention delivery

Of the 23 women, remaining after withdrawals, 18 received MSC (although one had their MSC confiscated by staff for administrative reasons). The remaining five women did not receive skin camouflage products before they were released or transferred.

The main barriers to women receiving the skin camouflage were prison factors. Two women missed multiple MSC appointments as a result of being in segregation. We were also informed that some women did not attend appointments because there was no prison staff escort, although these data cannot be distinguished from those who chose not to attend.

In the course of the research, we found that the prisoner who was responsible for booking appointments and distributing the camouflage products may have withheld the MSC from some women for personal reasons. Delivery of the MSC was also delayed for some women, because of delays in pharmacy ordering, or because the nurse prescriber was on leave.

These difficulties led us to pilot a revised methodology from 3 August 2017 to 24 May 2018. We worked closely with two new prisoner administrators and Safer Custody staff were responsible for MSC distribution. Our research assistant also spent additional time in the prison coordinating the process. During this time, eight women were randomised to the intervention group and the average time from baseline to receiving the MSC was reduced to 19 days (Range: 16–21) (removing one outlier whose MSC was delayed following segregation and participants who were transferred or released) from 49 days (range 26–79) (removing those who were transferred or released). These revised procedures improved delivery and ensured that the MSC was delivered within the required 3-week time-period.

Treatment fidelity

Peer-practitioners were observed at the end of their training to establish whether they could cover scars effectively. Ten percent of the MSC appointments were audio recorded and independently rated for fidelity to the manual. All practitioners followed most MSC procedures: clearly explaining the process, testing a range of products, explaining how to apply the MSC and checking that the participant was satisfied with the results. The practitioners were respectful and non-judgmental, although one made a comment about self-harm that could have caused distress.

Feasibility of outcome measure collection

WEMWBS, BDI-II, Adapted-DQLI and RSE were completed for all participants at follow-up. Three participants declined to complete the BSS at follow-up because they found it distressing. One participant declined to complete the BHS at follow-up but did not provide a reason. All of the psychosocial measures improved between baseline and follow-up for the intervention group and the control group. The study was not powered to detect significant between-group differences.

Feasibility of collecting self-harm incidents

Data were collected from the prison self-harm log for all participants, and from SystmOne for 93%. Participants' engagement with self-harm diaries varied, with an average of 45% of the diaries being completed per participant (range = 0–100%). Participant feedback identified the following reasons for non-completion: forgetting; struggling with literacy, concerns about the information being reported to staff, finding it hard to share information with the researchers, or finding the diaries repetitive.

Feasibility of collecting data for future economic evaluation

Descriptive statistics for EQ-5D-5 L and SF-6D at baseline are reported in Table 2. Baseline data were collected from 46 participants; 44 of whom were followed-up.

Table 2. Descriptive statistics for the outcome measures (all follow-up appointments are analysed together due to the close proximity between the post-intervention and follow-up measures for most participants).

		Intervention		Wait List Control	
		Mean	SD	Mean	SD
Adapted-DQLI[1]	Baseline	12.6957	3.95928	12.2609	6.51723
	Follow-up	6.7391	5.42902	11.9091	6.11718
BDI-II[2]	Baseline	33.6957	11.39950	38.9565	6.99011
	Follow-up	25.6957	16.93687	35.1364	8.45884
BHS[3]	Baseline	10.0000	5.86980	14.6957	4.43575
	Follow-up	7.3636	5.57670	12.0000	6.11010
BSS[4]	Baseline	6.2273	7.75783	8.8636	8.66463
	Follow-up	5.0435	10.20463	4.9412	6.76822
RSE[5]	Baseline	11.6522	4.68662	9.6087	3.38095
	Follow-up	14.8696	4.21366	12.1818	4.39303
WEMWBS[6]	Baseline	36.0435	11.17008	30.2609	9.12647
	Follow-up	40.1739	8.97295	30.8182	8.46076
EQ-5D-5 L[7]	Baseline	0.529	0.228	0.556	0.221
	Follow-up	0.587	0.231	0.575	0.204
SF-6D[8]	Baseline	0.645	0.113	0.566	0.083
	Follow-up	0.620	0.147	0.579	0.111

[a]The higher the score on the Dermatology Quality of Life Index, the more impaired the quality of life.
[b]0-13 indicates minimal depression; 14–19 mild depression; 20–28 moderate depression and 29–63 severe depression
[c]0-3 indicates No or minimal hopelessness; 4–8 is mild; 9–14 is moderate and 15+ is severe
[d]The higher the score, the greater the suicidal ideation.
[e]Higher scores represent higher self-esteem.
[f]Higher scores represent higher mental wellbeing.
[g]Higher scores represent higher health-related quality of life, where 1 represents full health.
[h]Higher scores represent higher health-related quality of life, where 1 represents full health.

The range of utility values was much smaller when measured using the SF-6D compared to EQ-5D-5 L. The level of missing responses to the EQ-5D-5 L questions was zero at both timepoints, suggesting that participants found the questionnaire acceptable. SF-6D utility scores were missing for two individuals at baseline and four at follow-up, which could suggest that the SF-6D was less acceptable.

Descriptive statistics for information collected on resource utilisation are presented in Table 3. Resource utilisation is summarised as the mean number of contacts per individual for whom this information was available. Data were collected retrospectively using prison records. This method of data collection relies on service use having been recorded in an individual's record. It was, therefore, very difficult to ascertain whether values should be zeros or

Table 3. Resource utilisation.

	Control arm (N = 23)			Treatment arm (N = 23)		
	Mean number of times accessed	SD	Number of individuals for whom information available	Mean number of times accessed	SD	Number of individuals for whom information available
Professional contacts inside secure facility						
GP	1.73	1.64	22.00	1.70	1.55	23.00
Nurse	4.95	4.43	22.00	5.78	4.75	23.00
Psychiatric nurse	4.09	4.74	22.00	5.57	7.67	23.00
Psychiatrist	0.41	1.01	22.00	0.87	1.42	23.00
Psychologist	0.09	0.43	22.00	0.09	0.42	23.00
Counsellor	0.00	0.00	22.00	0.22	0.85	23.00
Drug/alcohol treatment	0.77	1.45	22.00	1.30	2.51	23.00
Dentist	1.36	1.97	22.00	2.17	2.23	23.00
Optician	0.27	0.55	22.00	0.22	0.42	23.00
Chiropodist	0.09	0.43	22.00	0.17	0.49	23.00
Physiotherapist	0.09	0.43	22.00	0.17	0.58	23.00
Chaplain	5.20	10.55	5.00	3.13	5.11	8.00
Other (listed in free-text section)						
Specialist nurse	0.73	1.08	22.00	1.04	1.64	23.00
Female health	0.23	0.53	22.00	1.39	2.02	23.00
In possession	0.14	0.35	22.00	0.13	0.63	23.00
Mental health group	0.32	1.49	22.00	1.65	3.49	23.00
Midwife	1.36	6.40	22.00	0.04	0.21	23.00
Podiatry	0.05	0.21	22.00	0.00	0.00	23.00
Smoking cessation	2.41	3.08	22.00	3.09	3.37	23.00
X-ray	0.05	0.21	22.00	0.00	0.00	23.00
Hospital contacts inside secure facility						
Inpatient stays (healthcare wing)	0.00	0.00	22.00	0.00	0.00	22.00
Visiting specialists	0.00	0.00	22.00	0.05	0.21	22.00
Medication						
Number of medications prescribed	11.30	7.39	23.00	22.04	20.34	23.00
Hospital contacts outside secure facility						
Inpatient stays	0.10	0.44	21.00	0.09	0.42	23.00
Outpatient attendances	0.71	1.85	21.00	0.65	0.98	23.00
A&E attendances	0.10	0.44	21.00	0.30	0.88	23.00
External services used inside secure facility						

(*Continued*)

Table 3. (Continued).

	Control arm (N = 23)			Treatment arm (N = 23)		
	Mean number of times accessed	SD	Number of individuals for whom information available	Mean number of times accessed	SD	Number of individuals for whom information available
Samaritans (personal contacts)	0.67	0.58	3.00	0.75	0.96	4.00
Samaritans (phone calls)	0.00	.	1.00	0.00	0.00	2.00
Samaritans (letters received)	0.00	.	1.00	0.00	0.00	3.00
Citizens advice (personal contacts)	0.00	0.00	2.00	0.00	0.00	4.00
Citizens advice (phone calls)	0.00	.	1.00	0.00	0.00	3.00
Citizens advice (letters received)	0.00	.	1.00	0.00	0.00	3.00
Solicitor (personal contacts)	1.30	1.06	10.00	0.33	0.52	6.00
Solicitor (phone calls)	0.00	.	1.00	0.00	0.00	3.00
Solicitor (letters received)	0.00	.	1.00	0.00	0.00	3.00
Barrister (personal contacts)	0.00	0.00	2.00	0.00	0.00	4.00
Barrister (phone calls)	0.00	.	1.00	0.00	0.00	3.00
Barrister (letters received)	0.00	.	1.00	0.00	0.00	3.00
Legal advocate (personal contacts)	0.00	0.00	2.00	0.00	0.00	4.00
Legal advocate (phone calls)	0.00	.	1.00	0.00	0.00	3.00
Legal advocate (letters received)	0.00	.	1.00	0.00	0.00	3.00
Organised prison visitors (personal contacts)	0.00	0.00	2.00	0.00	0.00	4.00
Organised prison visitors (phone calls)	0.00	.	1.00	0.00	0.00	3.00
Organised prison visitors (letters received)	0.00	.	1.00	0.00	0.00	3.00
Probation officer (personal contacts)	0.33	0.58	3.00	0.20	0.45	5.00
Probation officer (phone calls)	0.00	.	1.00	0.00	0.00	3.00

(*Continued*)

Table 3. (Continued).

	Control arm (N = 23)			Treatment arm (N = 23)		
	Mean number of times accessed	SD	Number of individuals for whom information available	Mean number of times accessed	SD	Number of individuals for whom information available
Probation officer (letters received)	0.00	.	1.00	0.00	0.00	3.00
Police officer (personal contacts)	0.75	0.96	4.00	0.00	0.00	4.00
Police officer (phone calls)	0.00	.	1.00	0.00	0.00	3.00
Police officer (letters received)	0.00	.	1.00	0.00	0.00	2.00
Daily activities inside secure facility						
Therapeutic group	7.80	6.14	10.00	11.44	16.49	9.00
Creative activity	1.00	.	1.00	2.00	.	1.00
Work	78.47	24.19	15.00	63.56	53.46	18.00
Education	58.17	23.71	6.00	32.60	30.35	10.00
Sports activity	1.00	.	1.00	1.00	.	1.00

missing, as it is possible that individuals accessed services, and there is no way to verify this as it was not recorded.

Data on healthcare resource use was found to be available from SystmOne and could be used to collect healthcare resource utilisation in a future trial. Information on utilisation of external services and daily activities inside the facility was found to be less well recorded.

Acceptability

Overall, the women and staff who attended the interviews and focus groups found the intervention acceptable.

The women said that MSC:

- Increased confidence and self-esteem
- Reduced embarrassment
- They could wear shorts/vest tops in hot weather
- They had better relationships with staff
- They felt less judged by others
- They socialised and used the gym more
- They had more days when they felt good about themselves

One participant said that using the intervention had helped her to stop self-harming. Another described the intervention as 'almost like un-self-harming' and another said, 'it's like I'm wiping the bad parts of my life away'.

The only negative comments were that two women thought the colour match and coverage of the creams could have been improved.

Staff reported that they had not received complaints about the trial and that the few women who had spoken to them about it had said that the MSC made them more confident and was good quality. The staff said that it was a worthwhile intervention. Staff liked the peer-delivery model considering it empowering for the long-term prisoners. Staff suggested that MSC should be added to the women's property card to avoid confiscation.

Peer delivery

Of the total in the intervention group who completed a qualitative interview ($n = 18$), six women reported that they liked peer-delivery as the practitioners were understanding about self-harm. Six expressed concerns because: they were worried about confidentiality ($n = 1$); thought the appointment was rushed ($n = 2$); they would have preferred the research assistant to skin-match ($n = 1$); or did not think the practitioners were sufficiently confident or knowledgeable ($n = 2$).

The practitioners reported enjoying the training and said involvement increased their confidence and communication skills. They suggested that, in a future trial, we should provide additional formal supervision to help with the practical and emotional aspects of the role.

Discussion

Feasibility and acceptability of a full-scale RCT

This study examined whether it is feasible and acceptable to run a randomised controlled trial of MSC for self-harm scarring in English women's prisons. The results show that we can recruit and randomise participants to a trial and that our retention strategies can successfully ensure low attrition. Our attrition rate was similar to, or better than, a number of earlier RCTs in women's prisons (Lennox et al., 2017; Messina et al., 2010; Zlotnick et al., 2009). In particular, the rate was lower than an earlier feasibility and acceptability study of a self-harm intervention with women prisoners (Walker et al., 2017). The retention strategies we used are not only relevant for future trial design but can also be used by other prison researchers.

Women found randomisation acceptable within a wait-list control design and our groups were comparable on key factors suggesting that

randomisation was effective. In consultation, staff expressed concerns that women may be disappointed to be in the control group (personal communication, HMPPS). However, the COVER study demonstrates that this study design can be used successfully within a prison with participants finding the approach acceptable.

We can collect appropriate psychosocial outcome measures, which all improved for the intervention and control group. Researchers should be aware that some outcome measures, such as the BSS can be distressing for participants and care should be taken to ensure that there is support in place for participants where they are used.

The peer-delivered intervention demonstrated treatment fidelity and was acceptable to staff and six of the women who provided feedback (6 did not comment on acceptability and 6 had reservations about aspects of the model). Peer delivery of interventions in prison has been shown in previous research to be acceptable to participants and effective in improving health (Bagnall et al., 2015). A manualised training programme and peer-delivered intervention had the potential to facilitate sustainability if long-term prisoners were trained and could train additional practitioners, minimising any burden on prison staff.

The EQ-5D-5 L exhibited a greater range of utility scores than the SF-6D and was collected with zero missing data. This suggests that the EQ-5D-5 L would be the preferable measure for use in a future economic evaluation. Information on utilisation of external services and daily activities inside the prison was not routinely recorded in SystmOne or NOMIS. For a future trial, if these resources use categories are deemed important, alternative methods of data collection must be explored. In a future trial, an adapted version of the SFSUS should be co-created with prison personnel so the availability and location of the resource use data is confirmed. This is particularly important for future cost-effectiveness research, and for the prison system more widely, as currently little is known about the financial cost of self-harm in prisons.

Limitations

The main limitations of this feasibility study relate to aspects of intervention delivery. It was difficult for some women to receive the intervention in a timely manner. During this work, we have learned that intervention delivery can be improved by holding appointments at locations in the prison other than Safer Custody; which removes, to some extent, the need for escorts and missed appointments. After discussion with HMPPS, it is feasible to negotiate access to women in segregation in this way. Research staff should also be 'key-trained' (be able to carry prison keys independently) so they can move

freely across prisons. It is also advisable to involve more than one prescriber to account for leave.

Prisoner involvement in research administration can also be improved. It is prudent to involve more than one prisoner in project administration under closer supervision by prison and research staff to ensure that personal relationships between the women do not interfere with conducting the role. Peer-relationships between women in prison may be hostile or untrusting (Cantora et al., 2016) and this has the potential to affect the successful administration of this type of research.

Additional supervision for the peer-prisoners would support them and help to address participants' concerns about the competency of the practitioners. This would allow research staff to identify and address difficulties as they arise. With this adaptation, an acceptable peer-delivery service should be possible.

Although we collected adequate self-harm data from prison and healthcare records, collection from self-report diaries was less successful. Participants identified reasons why the data collection was difficult. Some of these can be overcome, for example, reminders can be sent to women using prison mail or IT appointment systems. However, other reasons such as reluctance to share information are harder to mitigate. Collecting accurate data on the frequency and severity of self-harm is the subject of ongoing debate (Borschmann et al., 2012; Owens et al., 2020). Relying on one data source for self-harm incidents in prison could substantially underestimate the actual number of events (Borschmann et al., 2012). It remains important that future research incorporates self-reported data as the study data showed that several self-harm incidents did not reach the attention of staff. Revised methods of self-report should be co-developed with women in prison to find an acceptable method.

Progress to the full-scale trial

This feasibility study was small and took place in one women's prison. However, the results suggest that it is feasible and acceptable to conduct a full-scale RCT of peer-delivered MSC for self-harm scarring in women's prisons. The results also provide a rationale for evaluating MSC for self-harm scarring in an RCT in other contexts, e.g., mental health care, building on a non-randomised pilot completed in 2016 (Ranote, 2016). This study revealed possible pitfalls and ways to mitigate against problems encountered by research in this environment. In addition, results from this pilot suggest the intervention has potential to improve well-being of women in prison.

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