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STUDY PROTOCOL

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# A hand-washing community-based educational intervention to reduce abscess incidence among people who inject drugs: a cluster randomised controlled clinical trial protocol (the HAWA study protocol)

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## Abstract

**Background** Besides the high prevalence of HIV and HCV infections, people who inject drugs (PWID) have a cumulative risk of acquiring skin and soft tissue infections (SSTI) from, among other things, social precariousness, homelessness/unstable housing, and unhygienic injecting practices. We propose to evaluate whether a two-component educational hand hygiene intervention which combines training in hand-washing with the supply of a single-use alcohol-based hand rub, called MONO-RUB, is effective in reducing injection-related abscesses in the PWID population. Specifically, we shall implement a nationwide, two-arm, multi-centre, cluster randomised controlled trial to evaluate the effectiveness and cost-effectiveness of this intervention in PWID.

**Methods** HAWA is a community-based participatory research study to be conducted in 22 harm reduction centres (HR) in France (not yet recruiting); the latter will be randomised into two clusters: centres providing standard HR services and the intervention (i.e., intervention group) and those providing standard HR services only (i.e., control group). After randomization, each cluster will include 220 PWID, with an inclusion period of 12 months and an individual follow-up period of 6 months. For each participant, we will collect data at M0, M3 and M6 from photos of injection sites on the participant's body, a face-to-face injection-related SSTI questionnaire, and a CATI questionnaire. The primary outcome is the reduction in abscess prevalence between M0 and M6, which will be compared between the control and intervention arms, and measured from observed (photographs) and self-declared (SSTI questionnaire) data. We will also assess the cost-effectiveness of the intervention.

**Discussion** The HAWA trial will be the first cluster randomized controlled trial to improve hand hygiene among PWID with a view to reducing SSTI. If effective and cost-effective, the intervention combined with the distribution of MONO-RUBs (or a similar cleaning product) may prove to be an important HR tool, helping to reduce the enormous burden of infection-related deaths and diseases in PWID.

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**Trial Registration** NCT06131788, received on 2 January 2024.

**Keywords** Hand hygiene, Injection, People who inject drugs, Randomized trial, Harm reduction

## Introduction

Recent reports provide alarming estimates for microbial infection prevalence among people who inject drugs (PWID) [1–4]. PWID vulnerability to microbial infections arises from, inter alia, intravenous drug injection practices that compromise skin integrity, thereby opening the way to pathogens [5, 6]. Skin and soft tissue infections (SSTI)—mainly manifested by abscesses and cellulitis—are the most widespread injection-related infections among this population, with up to one third of PWID reporting SSTI during the previous month and two-thirds during their lifetime [7, 8]. If left untreated, they can lead to life-threatening conditions such as an invasive bloodstream infections and endocarditis [9–11]. Although PWID represent a key study population for research on bacterial infection and microbial resistance, they are still omitted from related national representative surveys [3, 12].

Care for SSTI presents a major clinical problem for healthcare systems, often requiring visits to an emergency department [13, 14], hospitalisation [15], and surgical interventions [16]. Although treatments exist, infection control can prove difficult because of antimicrobial resistance [17–19]. Accordingly, the recommended strategy is to prevent SSTI from occurring in the first place. Many interventional trials using individual or structural approaches have highlighted significant reductions in bacterial infections from skin flora in various settings [20–23], including interventions focusing on hand hygiene [24, 25]. In general, these interventions have been found to be cost-saving or cost-effective in different settings; however, there is no specific evidence regarding their cost-effectiveness for the PWID population [26].

A large proportion of PWID do not systematically wash their hands before injection [27, 28], partly because many do not have access to running water and cleaning products prior to injection [29, 30]. In addition, a significant percentage experience social precariousness, especially homelessness and unstable housing [31], which exacerbates the problem of limited access to basic hygiene facilities in this community. These realities highlight the importance of developing an appropriate hand hygiene intervention that takes into account the specificities of the PWID community.

In a previous study, we evaluated the feasibility of a two-component educational intervention for PWID which combines training in hand-washing with the

supply of a single-use alcohol-based hand rub, called MONO-RUB [32]. Alcohol-based hand rubs have several advantages: they are quick to use, have optimal antimicrobial spectrum coverage, and do not require water [33]. The intervention was based on standard hand-hygiene healthcare recommendations, and was co-designed with field workers and PWID peers under the framework of community-based participatory research. The study found good acceptability and adoption of MONO-RUBs in the four participating harm reduction (HR) centres. Furthermore, results suggested it was effective in reducing injection-related infections, although this was not an outcome. Following up on this latter finding, we propose to implement a hand washing community-based educational intervention study, called HAWA, to specifically evaluate the effectiveness of this educational hand hygiene intervention on the reduction of injection-related abscesses among PWID.

HAWA has been designed as a nationwide, two-arm, multi-centre, cluster randomised controlled trial (cRCT). Self-reported and clinical data will be collected in order to measure the intervention-related outcomes, especially skin abscesses. Finally, the cost-effectiveness of the intervention will be also evaluated.

## Objectives

The main objective of the HAWA cRCT is to evaluate the effectiveness of an educational intervention for PWID which combines training in hand-washing with the supply of MONO-RUBs on the reduction of skin abscesses (both observed and self-reported).

The secondary objectives are as follows:

1. to measure the reduction in SSTI other than abscesses (e.g., cellulitis) and other infectious complications (venous damages, cotton fever, etc.);
2. to determine the impact of the intervention on hand hygiene practices when injecting, and in non-injecting contexts;
3. to measure the overall improvement in aseptic practices as part of an injection process (sterility of injection equipment, disinfection of the injection site, use of specific HR tools, etc.);
4. to measure compliance, tolerance (by measuring adverse events of MONO-RUB use) and satisfaction associated with the intervention;
5. to assess the intervention's cost-effectiveness.

## Methods

### Design

HAWA is a nationwide, community-based, prospective, multi-centre, cluster randomized controlled trial with a 1:1 two-arm allocation of participants. According to cluster randomisation, PWID will be assigned to *either* standard HR services plus an educational hand-washing intervention (which includes the distribution of MONO-RUBs) (hereafter the HAWA intervention arm,  $n=11$  clusters) *or* to standard HR services only (hereafter the control arm,  $n=11$  clusters). Participants will be followed-up for 6 months with follow-up visits at baseline, 3 months and 6 months.

### Educational hand-washing intervention

A trained HR centre staff will implement the educational intervention for each included PWID. A description of the intervention follows.

First, an educational session will highlight safer hygienic practices, reflecting work in our previous studies [34, 35]. Specifically, the staff member will highlight risky practices associated with injecting (including equipment sharing and reuse) and hygiene practices. He/she will also describe safer injection techniques [34] to limit the risk injection-related infectious disease transmission and other related complications [35].

Participants will then undergo a real-world hand-washing educational training session, as per our feasibility study [32]. This consists in the same HR centre staff member i) providing information about the origin of bacteria involved in injecting-related complications, ii) concentrating on the importance of disinfecting one hands prior to injection, and iii) teaching the three-step, 15-s, 'fingertips first', rubbing-based, hand-washing technique [36]. These three steps are as follows: a) pour all of the product into the palm of one hand; b) rotate the fingertips of each hand in the opposite palm, and c) rub both hands until dry. In addition, posters on the importance of hand washing and posters of the 3-step rubbing-based hand washing technique will be displayed in the intervention HR centres only.

Participants will then be provided with as many MONO-RUBs as they want as part of the intervention, and with sterile injection material as part of the routine HR services offer.

### Setting

Twenty-two HR centres managed by the French, community-based, non-governmental organization AIDES will be randomized either into the 'intervention' or 'control' arms. These centres will constitute the 22 clusters. HR centres offer unconditional welcome and support

to PWID during day-time hours, including the provision of injection equipment, advice about safer drug use, rapid testing for blood borne infections, primary health-care, food, and assistance concerning social security entitlements.

To ensure diversity in participant profiles, the trial will take place in 22 HR centres – which have already been selected—located in different cities across the 12 regions of mainland France as follows: Nouvelle Aquitaine ( $n=6$ ), Auvergne Rhône Alpes ( $n=2$ ), Provence-Alpes-Côte d'Azur ( $n=2$ ), Occitanie ( $n=2$ ), Grand Est ( $n=1$ ), Ile-de-France ( $n=1$ ), Bourgogne Franche Comté ( $n=2$ ), Centre Val-de-Loire ( $n=2$ ), Bretagne (Brittany) ( $n=1$ ), Hauts de France ( $n=1$ ), Normandie (Normandy) ( $n=1$ ) and Pays de la Loire ( $n=1$ ).

### Trial implementation: community-based participatory research approach

The HAWA study will be conducted using a community-based participatory research approach (CBPR). Academic researchers from the community-based research team SanteRCom (*Santé et Recherche Communautaire*), workers from AIDES, and members from Nouvelle Aube—an association of people who use drugs—will work together to implement every step of the trial. The work of the three partners is described in greater detail below.

SanteRCom is one of the three academic research teams of the UMR 1252 SESSTIM research unit. It conducts public health and interdisciplinary research in the field of HIV, hepatitis C and HR. It will supervise the methodological and scientific aspects of the trial.

AIDES is the main community-based NGO fighting against HIV and hepatitis in France. It conducts information, prevention, support, CBPR and advocacy campaigns for key populations affected by or at high risk of HIV and hepatitis. These include men who have sex with men, sex workers, transgender people, migrants, prison inmates, and people who use drugs. AIDES will be a scientific partner in the project, will conduct the operational aspects of the trial, act as the primary link with the participating HR centres, and collaborate in the construction of the survey tools.

The self-support association Nouvelle Aube is an NGO representing people who use drugs, including PWID. Its principal activities include prevention, HR and health promotion for vulnerable and stigmatised people, a population particularly at risk of having HIV, hepatitis, and sexually transmitted infections. Nouvelle Aube will be actively involved in the development of the trial's educational hand-washing intervention training, ensuring that it meets the real-world needs of the PWID community. It will also collaborate in the construction of the survey tools and the pilot phase.

### **Pilot phase**

A pilot phase will be performed before the intervention trial is implemented. The objectives of this pilot phase will be to test the questionnaires, to evaluate compliance with research guidelines, and to assess the quality of the measurements collected and the methods used. It will take place for a one-month period in Nouvelle Aube's premises. Participants in the pilot phase will not be retained for the intervention trial.

### **Intervention trial study population**

#### ***Inclusion criteria***

Inclusion criteria are as follows: over 18 years old, French-speaking, reporting to have injected illicit (heroin, cocaine/crack, amphetamines, ecstasy, etc. except cannabis) or prescription (methylphenidate, buprenorphine, benzodiazepines, morphine sulphate, oxycodone, etc.) drugs at least once during the previous week, and providing free and informed consent to participate.

#### ***Exclusion criteria***

Exclusion criteria are as follows: not regularly going to the participating HR centre in the relevant city, having an alcohol and/or alcohol-based hand rub (ABHR) excipient intolerance/allergy, being under legal protection (guardianship or judicial protection).

#### ***Recruitment***

Trial recruitment will begin in the first semester of 2025 for a twelve-month period. The staff in the 22 participating HR centres will identify regular PWID visitors, and ensure that all potential participants meet all the inclusion criteria before being solicited to participate.

#### ***Sample Size***

To calculate the required number of participants, we hypothesize that the prevalence of abscesses will reduce from 30 to 15% in the intervention arm compared with the control arm, where it shall remain at 30%. In other words, a difference in abscess prevalence of 15% between the two arms is forecast between M0 and M6: i.e., a binary outcome. In order to guarantee a power of at least 90%, with an alpha risk of 5%, we estimate that each cluster must contain at least 15 participants. This calculation is based on the following two hypotheses: a cluster auto-correlation (i.e. correlation of a given cluster's outcome at different times) and individual auto-correlation (i.e. correlation of outcomes for a given individual at different times) of 80%, and a within-period intra-cluster correlation coefficient (ICC,  $\rho$ ) between 0.01 and 0.02 as recommended for human

studies [37]. However, this coefficient can be adapted if needed according to the data from the pilot phase. We hypothesize that one third of the participants in each cluster will be lost over the 6-month follow-up. Accordingly, to ensure a total of 300 participants (150 per arm) in the 22 clusters (i.e., 11 intervention clusters and 11 control clusters) at the end of the study (M6), at least 440 participants must be recruited for the intervention trial.

#### ***Participant withdrawal***

We expect the participant withdrawal rate (and therefore loss to follow-up) to be low for two reasons: i) respondents will be compensated for their participation (see details in the relevant section), and ii) one of the exclusion criteria is that participants are not regular HR centre visitors.

### **Cluster description**

#### ***Cluster randomization***

Each of the 22 HR centres will be randomized either into the 'intervention' or 'control' arm before the launch of the main study using computer software. Centres were selected to ensure they are geographically distant from one another. There shall be one centre per county (note: each of the 12 regions included comprise several counties). This choice will ensure that the risk of 'contamination' between the two arms is minimised, that is to say that the control arm cannot be influenced either by the educational hand-washing component of the intervention or by the distribution of the MONO-RUBs. All visitors to a HR centre who meet the study inclusion criteria will be solicited to participate. Those who agree will be recruited into the relative study arm (i.e., intervention or control).

#### ***Comparator***

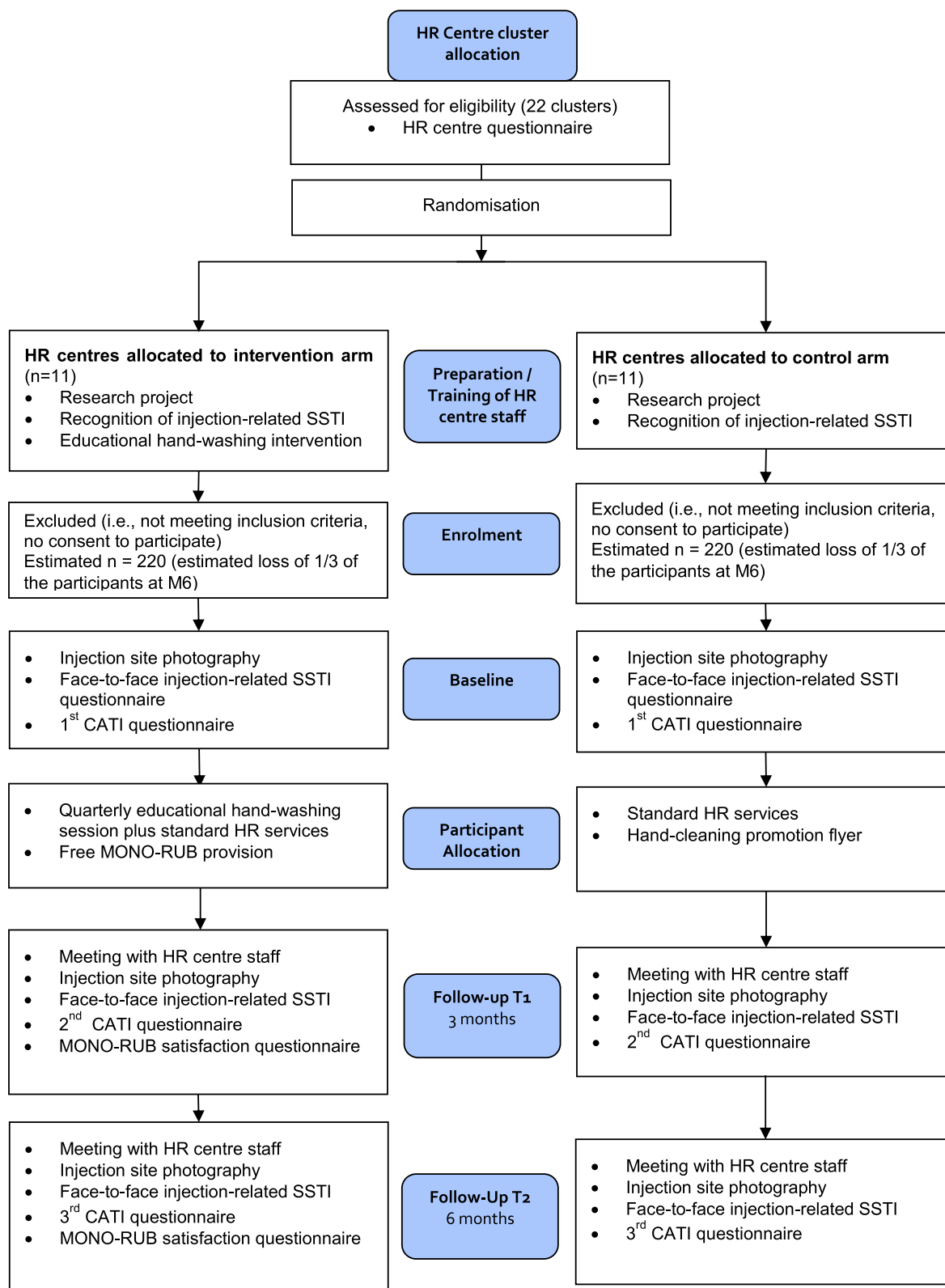
The 11 control arm HR centres will constitute the control arm. Participants in this arm will receive standard HR services (distribution of sterile equipment, information on drug use prevention and orientation to adequate services).

#### ***Control arm HR centre compensation***

Once the study has been completed, staff in the control HR centres will be trained in providing the educational intervention. All visitors to those HR centres will then be offered the intervention plus an unlimited supply of MONO-RUBs for a 6-month period gratis.

### **Procedure**

Figure 1 presents the trial flowchart and data collection at each time point. Table 1 presents the assessment



**Fig. 1** Flowchart. Effect of the combined standard HR services plus educational hand-washing intervention *versus* standard HR services only in reducing abscesses: a cluster randomized controlled trial (CRCT)

**Table 1** Enrolment, intervention and assessment schedule. AUDIT-C = Alcohol Use Disorders Identification Test–Consumption

	Cluster allocation	Study period		
		Baseline visit	Follow-up visits	
		0 months	3 months	6 months
<b>HR centre preparation</b>				
Randomisation	X			
Staff preparation	X			
<b>Enrolment:</b>				
Eligibility screening		X		
Informed consent		X		
<b>Interventions:</b>				
Standard HR services			X	X
Educational hand-washing intervention			X	X
MONO-RUB provision			X	X
<b>Assessments:</b>				
HR centre questionnaire	X			
HR centre staff face-to-face measures				
Injection site photography		X	X	X
Most recent injection practices		X	X	X
CATI questionnaire measures				
Socio-demographic characteristics		X		
Socioeconomic characteristics		X	X	X
Previous drug consumption history		X		
Current drug consumption		X	X	X
AUDIT-C		X	X	X
Injection practices and equipment use		X	X	X
Hand hygiene practices		X	X	X
MONO-RUB use & satisfaction			X	X
(Educational hand-washing arm only)				
Injection-related complications		X	X	X
Use of healthcare services		X	X	X
Health Related Quality of Life (EQ-5D-5L)		X	X	X
Assessment of primary outcome		X		X

schedule at baseline and the two follow-up visits at M3 and M6.

#### HR centre staff training

The project will start by training staff from the 22 participating HR centres about the HAWA research project using a three-part preparation programme which will focus on i) the details of the project, ii) how to recognize injection-related SSTI, and iii) the project's educational hand-washing intervention (only for staff from HR centres in the intervention arm). These three elements are described in greater detail below:

#### Details of the project

The research project will be presented to HR centre staff by members of the SanteRcom research team and AIDES's officer-in-charge. This will consist in describing the general aspects of CBPR, and the specific details

of HAWA, including the project's objectives, the documents required for the trial, the enrolment, intervention and assessment schedule, training on how to correctly collect data from participating PWID, and the expected operational impact of the study. All data except for the CATI questionnaires will be collected using computer tablets provided to the HR centres specifically for this project; accordingly, HR staff will be trained in using this technology.

#### Recognizing injection-related SSTI

An experienced nurse employed by Nouvelle Aube will train HR centre staff in how to recognize injection-related SSTI (abscesses, cellulitis, etc.) and how to photograph them correctly with the computer tablet. This training is essential as it will be the HR centre staff who will interview the participants about injection-related

complications, features, and the frequency of injection-related SSTI occurrence.

#### **Educational hand-washing intervention**

Only staff from HR centres in the intervention arm will be trained in the educational hand-washing intervention. This training will be provided by a three-member team (one professional from SanteRcom, one from Nouvelle Aube, and one from AIDES).

#### **Participant eligibility assessment**

Participants will be screened for eligibility (see ‘Study Population—inclusion criteria’ section above) by the HR centre staff.

#### **Consent**

Participants who agree to participate and who meet all eligibility criteria must be allowed to read both the research project information note and the participation consent form in a free and well-informed manner. Once the potential participant has read the information note, he/she can then decide to provide consent or not. Providing consent will mean agreeing to participate in 3 computer-assisted telephone interviews (CATI), having parts of one’s body photographed, and participating in the 6-month follow-up.

#### **Refusal questionnaire**

Persons who refuse to participate will be asked to complete a short refusal questionnaire containing five questions about their age, gender, type of housing, most recent drug used and administration route, and finally their reason(s) for refusal. Data from this questionnaire will allow us to compare participant and non-participant profiles to evaluate the representativeness of the recruited sample.

#### **Participant compensation**

To compensate participants for the time they devote to this study, 10 euros will be provided in the form of a voucher for each completed questionnaire. Moreover, 20 euros, also in the form of a voucher, will be provided at the end of the study to those who complete follow-up and all three study CATI questionnaires (see Procedure, Flowchart, Fig. 1 above). The aim of the latter compensation is to ensure participant retention.

#### **Study instruments**

Table 1 presents the assessment schedule for HAWA. The data collected will be recorded in four different formats: a HR centre questionnaire, photos of the injection sites on the participant’s body, a face-to-face SSTI questionnaire,

and the three CATI questionnaires. The four formats are described below.

All data will be stored on a single secure computer tablet provided to each HR centre specifically for the project.

#### **HR centre questionnaire**

Each participating HR centre (i.e., both intervention and control clusters) will complete a questionnaire providing the following structural data:

- staff composition: number and type of professionals working in the centre, time dedicated to the educational intervention (for the intervention arm);
- a description of the active client file: number and profiles of clients per month, number of PWIDs, median age, sex repartition.
- public opening hours.
- whether or not there is a dedicated PWUD reception area.
- HR services provided: HR services linked to hygiene and injection practices (needle exchange program, education in safer injection practices, other intervention related specifically to hand hygiene, drug consumption room, outreach interventions).

This questionnaire will be used in the data analyses to adjust for structural variables that may influence the effect of the intervention. The data collected will also be used for the economic evaluation of the intervention.

#### **Photos of injection sites on the participant’s body**

Clinical data will be collected by examining photographs of current injection sites. Ideally, these photos should be taken by the HR centre staff member who implements the intervention. If participants categorically refuse to have photos taken by a third party, then they can take photos themselves; these should subsequently be checked by the HR staff member to ensure they are clear and that they guarantee anonymity. Intimate areas will be photographed by the participants themselves.

#### **Face-to-face injection-related SSTI questionnaire**

An injection-related SSTI questionnaire will be completed by a HR staff member, with a specific section focusing on abscesses. Abscess-related data will include the approximate date of apparition, location, and frequency of occurrence of the SSTI. Data on treatment for abscesses will also be collected.

#### **CATI questionnaires**

An appointment for each of the three CATI questionnaires will be set by the HR staff member at the end of the face-to-face SSTI questionnaire. Each CATI



questionnaire will be administered by a trained interviewer from the SanteRCom research team. The first questionnaire (i.e., at M0) must occur before the educational hand-washing intervention starts, but after the injection site photos have been taken. Each questionnaire must be scheduled sometime in the 7 days after the relevant (i.e., M0, M3 and M6) photos have been taken, in order to ensure a link between observed SSTI clinical data (i.e., photo-based) and CATI data on injection practices. If this timeframe is not met, the photos must be taken again.

The next section describes the CATI questionnaires in much greater detail.

### **CATI questionnaires**

There are three CATI questionnaires: one at the baseline visit (i.e., M0), and one at each of the two quarterly follow-up visits (i.e., M3 and M6). Two types of data will be collected as follows: i) non-varying data (e.g., date of birth, drug consumption history), which will only be collected at M0; ii) varying data, which require longitudinal observation (e.g., socio-behavioural data). These will be collected at M0, M3 and M6. The data to be collected are described in greater detail below:

#### ***Socio-demographic and socioeconomic characteristics***

Socio-demographic characteristics including gender, age, country of birth, education level, employment status, marital status, and parenthood, will be collected. Socioeconomic and housing data will also be collected including employment, social welfare allowances, health assurance, food insecurity, current housing status including type of housing, housing quality, access to water, and how frequently the participant slept rough during the previous month.

#### ***Alcohol use***

We will use the Alcohol Use Disorders Identification Test (AUDIT-C) scale to identify the level of alcohol consumption. This will be measured at baseline and at both quarterly follow-up visits.

#### ***Past and current drug consumption and practices***

Age at first drug injection will only be collected once (M0). Data on drug use patterns will be collected in all three CATI questionnaires. These data will include: current substances used, consumption frequency, and mode of administration (injection, inhalation, sniffing, smoking, or ingesting). A set of injection-specific questions will also be asked, including the drug use context (private or public place), whether the participant is injected by someone else, whether he/she injects someone else, and the primary and occasional body injection sites they use.

Data on other injection practices will also be collected including the sharing of syringes/needles or other injecting paraphernalia (filters, swabs, water, cups, etc.) and skin cleanliness prior to injection.

#### ***Most recent injection practices***

A set of questions will collect data on the participant's practices during his/her most recent injection. These will collect data on the context (i.e., private or public place), the substance injected, the paraphernalia used, as well as preparation and injection procedures. These data on the most recent injection will help to limit memory bias on injection practices.

#### ***Injection-related complications***

Data on injection-related wounds, such as redness or vascular damage, will be collected, as will data on complications associated with injection, such as cotton fever.

#### ***Hand-hygiene practices***

Data on practices specifically associated with hand-hygiene, such as hand-washing frequency in general (i.e., not necessarily when injecting drugs), the products most often used for hand-hygiene (whether sterile or not), and the technique used, will also be collected.

#### ***MONO-RUB use compliance***

For the intervention arm, the use of MONO-RUBs and unintended consequences will be measured using a specific section in the two CATI questionnaires at M3 and M6 visits. The data collected from this section will provide information on participant compliance to MONO-RUB use, and on whether the MONO-RUBS are being diverted (e.g., drunk or used to disinfect other persons' skin) [32].

#### ***Healthcare utilization and HIV/HCV serological status***

The following elements of healthcare utilization will be investigated: access to specialized services and physicians, emergency department visits, and visits to addiction centres or other structures providing HR services. Participants' health issues will also be investigated, specifically through the collection of data on opioid agonist treatment prescription, overdoses, and HIV and HCV serostatus.

#### ***Health-related quality of life***

Another section of the 3 CATI questionnaires will measure health-related quality of life (HRQoL), using the EQ-5D-5L questionnaire items (developed by the Euro-QoL Group [38]). as recommended by France's National Authority for Health (*Haute Autorité de Santé* (HAS)) [39, 40].

## Outcome measures

### Primary outcome

To measure the effectiveness of the educational hand-washing intervention, the primary outcome will be the reduction in abscess prevalence between M0 and M6. This prevalence will be measured at M0 and M6 from observed and self-declared data, collected from the injection-site photographs and the face-to-face injection-related SSTI questionnaire, respectively (see sections above for details).

### Secondary outcomes

There are three secondary outcomes as follows: i) the change in incidence of injection-related SSTI complications other than abscesses (e.g., cellulitis, skin ulcers). This will be assessed using the injection site photographs and the face-to-face injection-related SSTI questionnaire; ii) the improvement in injection practices in terms of hand-hygiene directly linked to the educational hand-washing intervention. This will be determined using data from the three CATI questionnaires (see the sub-section ‘[Hand-hygiene practices](#)’ above) and by assessing the use of sterile equipment, equipment sharing, and injection into a dangerous body site; iii) for the intervention arm, MONO-RUB use compliance (see relevant section above) and adverse events will also be measured.

### Analyses

Statistical analyses for the primary outcome will involve comparing the reduction in abscess prevalence in the intervention arm with that in the control arm. As stated above, no reduction is expected in the latter. These analyses will be performed using the injection-site photographs and the injection-related SSTI questionnaire. Logistic regression models taking into account repeated measures (e.g., generalized estimating equation models) will be built to study the factors associated with the occurrence of abscesses.

Process outcomes analyses will be performed using mixed models (logistic if the response variable studied is dichotomous, linear if the response variable is quantitative or semi-quantitative, and Poisson for count variables). Intra-cluster correlation will be taken into account when making estimations using multi-level models.

The data will be analysed by a statistician using STATA and R software. Future related scientific publications will be open access.

### Economic evaluation

We will perform a model-based cost-effectiveness analysis to make projections of the effectiveness, the cost, and the cost-effectiveness of the educational hand-washing intervention combined with the provision of

MONO-RUBs over the long-term (10 years) in a hypothetical context of intervention scale-up. Analyses will be conducted from the perspective of the health system.

To perform this analysis, a static, population-based simulation model will be designed to make projections of the public health and economic impacts of the intervention in PWID cohorts that frequent HR centres in France. We will simulate PWID cohorts under two scenarios: one where the educational intervention does not exist (i.e., the current situation), and one where it does. This model will include the incidence of skin wounds, such as injection-related SSTI, and progression to related complications, specifically necrosis, septicaemia, and endocarditis. It will also account for associated healthcare consumption (medical consultations, emergency room visits, and hospitalisations) for injection-related SSTI events, and mortality associated with severe complications (which will be assessed by a literature review). Medical costs (in euros) associated with each of these medical events will be estimated from published literature and publically available French health insurance data (<https://www.scansante.fr/>). The model will also include the cost of the intervention using the data collected in each HR centre questionnaire. Finally, it will use utility scores to assess the HRQoL of participants in both the intervention and control arms.

The incidence rates of injection-related SSTI and associated complications, as well as the impact of the intervention on the latter and on HRQoL, will be estimated from the study results.

The effectiveness indicators of this part of the analysis will be evaluated over the lifetime of the simulated cohorts and will include the following: the number of life-years saved and the number of quality-adjusted life-years (QALYs) saved thanks to the intervention, the incremental cost of the intervention (*versus* the current situation) in euros, and the incremental cost-effectiveness ratio (ICER) in euros/QALY saved thanks to the HAWA intervention. As the *Haute Autorité de Santé* (French National Authority for Health) does not provide recommendations on what cost-effectiveness thresholds to use in France [40], we will use the following threshold, suggested by the World Health Organization [41]: i) very cost-effective if the ICER is less than one times the French per-capita gross domestic product (GDP) (approximately €33,000 in 2022), and ii) cost-effective if the ICER is less than three times the 2022 French per-capita GDP (€99,000). We will also use a second, more realistic approach to define the cost-effectiveness threshold in France, based on the ICERs of interventions which national health authorities consider to be worthy of national health insurance funding (e.g., 30,000–35,000 euros) [42]. Finally, we will also perform deterministic sensitivity and probabilistic

sensitivity analyses to assess the impact of uncertainty in parameter estimates on our results.

#### Data management and monitoring

The tablet computer provided by the research team to each participating HR centre in order to collect data will contain all the study documents (i.e., injection-site photographs and all questionnaires) except the paper-based consent forms. The tablets will be connected to a secure academic cloud server located in Europe where the information will be stored. Data will be stored in real-time, allowing the research team to continuously evaluate its quality, and will be captured by the HR staff using suitable survey software installed on the tablets. The tablets themselves will be protected with antivirus software and a password known only to the HR staff. All collected data will respect the European General Data Protection Regulation concerning data transfer (i.e., transfer outside France will not be permitted), storage (i.e., protection procedures to access the data and the cloud servers will be located in Europe), and analysis (i.e., only the analyses mentioned in the project protocol will be performed). To ensure maximum protection of the sensitive data collected, a study identifying privacy and other risks will be conducted. An MR0003-type compliance undertaking will be filed with the French Data Protection Authority (CNIL) as per national research regulations.

#### Discussion

The aim of the HAWA trial study is to evaluate the effectiveness of an HR centre-based educational hand-washing intervention combined with the distribution of a single-use alcohol-based cleaning product (called MONO-RUB) on reducing abscess incidence in PWID. If this intervention does indeed decrease abscess occurrence in the study population, we can expect that it will have a much broader impact on other injection-related SSTI—such as skin ulcers, cellulitis, endocarditis and sepsis—and on hospitalisations.

To date, most HR services to decrease the incidence of transmissible infections among PWID have centred on providing sterile equipment [43–45]. Although many studies have identified the sharing of injection equipment as a factor for microbial transmission [6, 46], the prevalence of bacterial infections among PWID who take advantage of needle and syringe programs is still high [47, 48]; this would suggest that practices other than equipment-sharing are responsible for SSTI, including poor hand-hygiene and the reuse of injecting equipment. However, no specific hand-hygiene educational intervention or suitable hand-washing tool is currently available in HR programs for PWID in France. We believe that the combined intervention offered in the HAWA trial may

represent the missing infection prevention link. If our study provides positive results, then this work should lead to the promotion of greater access to hand-hygiene products and tools. It should also stimulate practical reflection on new HR tools.

PWID participant acceptability of MONO-RUBs is a crucial element of the intervention's success. During our related feasibility study [32], 50% and 61% of participants reported that MONO-RUBs had become the main product they used for hand hygiene at 2 and 6 weeks, respectively; these results reflect good acceptability. Many PWID have precarious living conditions with limited access to water and to hand-hygiene products. The results from our feasibility study underline the importance of supplying hand-hygiene products, cleaning products for injection sites, and specific education to this population.

We believe that the CBPR approach used in HAWA will lead to effective implementation of the educational intervention. As the intervention itself was co-developed with field workers from the association AIDES and with PWID who are members of the Nouvelle Aube drug users' association, the intervention protocol is based on several recommendations from community-based peers [29, 49, 50]. These include i) ensuring that the verbal education session is not overly long and is performed by a trustworthy person in an environment conducive to discussion about practices, ii) unlimited access to MONO-RUBs during the study and for six months after it ends, and iii) the need to have a hand-hygiene product whose use is adapted to the various constraints in terms of injection for PWID.

As a CBPR project, HAWA will help train HR centre staff and PWID from Nouvelle Aube in the various aspects of performing scientific research. Moreover, this meaningful and active participation in research will enable them to improve their power to act and their involvement in encouraging societal change [51]. In addition, in a previous study [52], our team showed that in order to ensure that participants rigorously comply with the research process, and advocate the dissemination of results, it is crucial to involve field workers in the evaluation of implementation research and field-based interventions.

The HAWA trial will be the first cRCT to target microbial infections among PWID in HR centres in France. If shown to be effective and cost-effective, the educational hand-washing intervention combined with the distribution of MONO-RUBs (or a similar cleaning product) may prove to be a HR tool which is just as useful as the provision of sterile equipment (i.e., current standard HR service). In this way, it may help to reduce the enormous burden of infection-related deaths and diseases in PWID.

To conclude, if successful, the HAWA trial will raise awareness among clinicians and policymakers about how to prevent microbial infections among PWID—a key hard-to-reach population—and will initiate reflection on the poor day-to-day living conditions of many persons in this population, especially the lack of sanitation facilities and suitable housing.

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#### Authors' contributions

Study conception and design: PR, LST, JL, SDB, AC, LP, LB, MA. NG, LB and MA drafted the first manuscript. PR, MC, DM, AC, SDB, LST, MLS, LBM, and CL revised the manuscript. All authors substantially contributed to the manuscript and approved the final version

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#### Data availability

No datasets were generated or analysed during the current study.

#### Declarations

##### Ethics approval and consent to participate

The HAWA trial has already received ethical approval from the Comité de Protection de Personnes (IRB00003888; IORG0003254; FWA00005831). The clinical trial was registered on ClinicalTrials. Gov under the ID number NCT06131788 (2024-01-02). Participants who agree to participate and who meet all eligibility criteria will give their signed consent.

##### Consent for publication

Not applicable.

##### Competing interests

The authors declare no competing interests.

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