Study Protocol
(Epi & non-clinical studies)

"hands4health: Hand hygiene, water quality and sanitation in schools not connected to functional water supply system: a cluster-randomized controlled trial in Nigeria and Palestine"

Type of Research Project	Research projects (HRO) - Research projects – involving measures or sampling of biological material or collection of health-related data from persons.

Study acronym/ID	H4H		
Protocol Version Nr	1.0	**Date**	02.06.2023
Project Leader / Responsible	Prof. Dr. Mirko Winkler Swiss Tropical and Public Health Institute Kreuzstrasse 2 4132 Allschwil Phone: +41612848339 mirko.winkler@unibas.ch		
Funding Agency	Swiss Agency for Development and Cooperation (SDC) Freiburgstrasse 130 3003 Bern		

1 General Information

I. List of Project Leaders and other key persons involved in the study

Title	Names	Institution	Position	Function in study
Prof. Dr.	Mirko Winkler	Swiss TPH	Group Leader	PI of the present study
Dr.	Maryna Peter	FHNW	Group Leader	Lead of the H4H project and lead at FHNW
	Bruno Pascual	Terre des hommes Lausanne	WASH Advisor	WASH coordinator at Terre des hommes Lausanne
	Zainab Abdulkarim	Terre des hommes Nigeria	WASH responsible	Lead of Terre des hommes Nigeria
	Roberto Turcato	Cesvi	Technical Coordinator	Lead of Cesvi Palestine
	Issa Younan	Cesvi	Local Coordinator	Local WASH coordinator
Dr.	Andrea Tamas	Ranas Ltd.	Senior Behaviour Change Expert	Behaviour Change work package
Dr.	Jan Hattendorf	Swiss TPH	Scientific Project Leader	Statistician
	Yaman Abuzahra	Swiss TPH	PhD Candidate	Investigator
	Rena salzmann	Skat Foundation	Programme and communication officer	Knowledge broker

The project leaders are qualified individuals by education and training and are responsible for the whole project. All further key persons are also qualified by education and training to perform their assigned tasks and responsibilities.

II. Signatures

Study Title **hands4health: Hand hygiene, water quality and sanitation in schools not connected to functional water supply system: a cluster-randomized controlled trial in Nigeria and Palestine**

The following project leaders have approved the protocol version ***[1.0 (dated 02.06.2023)]***, and confirm hereby to conduct the project according to the current version of the Declaration of Helsinki /, and Essentials of Good Epidemiological Practice issued by Public Health Switzerland (EGEP) / ISO EN 14155 / CIOMS International Ethical Guidelines for epidemiological studies 2009 as well as all national legal requirements and guidelines as applicable.

Project Leader

- I have read this protocol (*version 1.0, dated 02.06.2023*) and agree that it contains all necessary details for carrying out this study. I will conduct the study as outlined herein and will complete the study within the time designated.
- I will ensure that all individuals and parties contributing to this study are qualified and I will implement procedures to ensure integrity of study tasks and data.
- I will provide copies of the protocol and all pertinent information to all individuals responsible to me who assist in the conduct of this study. I will discuss this material with them to ensure they are fully informed and trained regarding their activities within the study conduct.
- I will use only approved informed consent forms and will fulfil all responsibilities for submitting pertinent information to the Independent Ethics Committees responsible for this study.
- It is understood that this protocol will not be disclosed to others without prior written authorisation from the Project Leader or Sponsor, except where required by applicable local laws

Project Leader (lead centre/site)

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III. Abbreviations / Glossary of terms

CFU	Colony-Forming Unit
COVID-19	Coronavirus Disease 2019
cRCT	Cluster-Randomized Controlled Trial
CRF	Case Report Form
Eawag	Swiss Federal Institute of Aquatic Science and Technology
EPFL	Ecole Polythechnique Fédérale de Lausanne
FACET WINS	Facility Evaluation Tool for WASH in Schools
FGD	Focus Group Discussion
FHNW	Fachhochschule Nordwestschweiz
H4H	Hands4Health
HRO	Ordinance of Human Research with the Exception of Clinical Trial (Switzerland)
ICF	Informed Consent Form
IDP	Internally Displaced People
IEC	Independent Ethics Committee
ICP	Infection Prevention and Control
JMP	Joint Monitoring Programme
KII	Key Informant Interview
LDCs	Least Developed Countries
LMIC	Low and Middle-Income Country
MCI	Multi-component intervention
NGO	Non-Governmental Organization
ODK	Open Data Kit
RANAS	Risk, Attitude, Norm, Ability and Self-regulation
SDC	Swiss Agency for Development and Cooperation
SDG	Sustainable Development Goal
Swiss TPH	Swiss Tropical and Public Health Institute
Tdh	Terre des hommes
ToA	Theory Of Action
ToC	Theory Of Change
UNICEF	United Nations Children's Fund

WASH	Water, Sanitation and Hygiene
WHO	World Health Organization

IV. Synopsis

Project Leader	Prof. Dr Mirko Winkler
Study Title	hands4health: Hand hygiene, water quality and sanitation in schools not connected to functional water supply system: a cluster-randomized controlled trial in Nigeria and Palestine
Short Title/Study ID	Hand hygiene intervention in schools- H4H
Protocol Version and Date	Version 1.0, 02.06.2023
Study Category with Rationale	Non-clinical study, risk category A: no drugs are being tested, and only hand-rinse samples are being taken
Background and Rationale	Despite the effectiveness of hand hygiene in reducing the transmission of infectious diseases – as demonstrated by the COVID-19 pandemic – 2.3 billion people – primarily located in low- and middle-income countries (LMICs) – are exposed to increased risk of infectious diseases as a result of lack of access to water and hygiene services. Improving hand hygiene is most challenging in humanitarian contexts, where challenges in water availability and quality in combination with overcrowded conditions often limit access to sanitation and hygiene services. Schools are one of the most critical places where adequate water, sanitation and hygiene (WASH) should be provided in such settings. Against this background, the Hand4Health (H4H) project will implement a multicomponent intervention (MCI) designed to improve hand hygiene and access to water for students in schools not connected to functional water systems in Nigeria and Palestine by providing them with a sustainable handwashing system and a package of systematic handwashing-behaviour change activities.
Objective(s)	**Primary objective:** Evaluate the effects of the H4H multi-component intervention (MCI) package on hand hygiene of primary school students in Nigeria and Palestine. **Secondary objectives:** 1) Evaluate the effects of the H4H MCI package on the well-being of primary school students in Nigeria and Palestine 2) Assess the impact of the H4H MCI package on hygiene-related risks, attitudes, norms, abilities and self-regulation (RANAS) behavioural factors of primary school students in Nigeria and Palestine 3) Assess the effect of the H4H MCI package on absenteeism incidence and hygiene-related health outcomes of primary school students in Nigeria and Palestine 4) Explore the associations of personal, physical and social contextual factors with hand hygiene and the well-being of primary school students in Palestine 5) Explore the perceived impacts of the H4H MCI package on the health and well-being of primary school students in Nigeria and Palestine

Primary Endpoint Secondary Endpoints	The **primary endpoint** of this study will be good handwashing practice defined as students who wash their hands with water and soap before eating assessed by structured handwashing observations. The **secondary endpoints** are: A) Good handwashing practice defined as students who wash their hands with water and soap after using the toilet assessed by structured handwashing observation B) Self-reported handwashing practice answered for two critical events; before eating and after using the toilet, on a Likert scale ranging from almost never to almost always. C) The well-being of students assessed by KINDL tool D) Number of total coliforms and E.coli colony-forming units (CFUs) per hand before handwashing. E) Hygiene-related health outcomes and absenteeism incidence. The health outcomes will be reassessed with local experts in the country to assure feasibility before the start of the intervention.
Study Design	**Overall project:** Multi-center cluster-randomized controlled trial (cRCT) design. Module 1-3 will be repeated three times within the cRCT at baseline, three months post-intervention and at endline. Module 4 data collection will take place in both study arms longitudinally starting after the intervention has been implemented. Module 5 will be a self-reported survey administered for the parents of the students included in the study at baseline in Palestine. Module 6 and 7 are qualitative focus group discussions (FGDs) and interviews and will take place after the second round of data collection in Modules 1-3.
Inclusion/Exclusion Criteria	Study participants are primary school students aged 10-12 years attending eligible schools that were selected to be included in this study. **Inclusion criteria Modules 1-4:** Schools were selected based on accessibility for the study teams, not having a water source directly connected to the building of the school, having primary grades (5^{th}-7^{th}), having ≤ 7000 students and being impacted by conflict. 50 students will be randomly selected from one or two classes in the included schools and they must fulfil all the inclusion criteria: - Age between 10-12 years or attending grades 5^{th}-7^{th} - Students, male and female, who are in classes close to where the handwashing stations (Gravit'eau) will be positioned in the school (in Nigeria) - Students must be in the same school for the course of the study (1 year). **Exclusion criteria Modules 1-4:** students must not fulfil any of the following exclusion criteria: - Refusal to participate by not providing signed consent forms or oral assent - having any medical condition that prevents them from washing their hands - having unexplained intermittent attendance in school (school teachers will be consulted and school's absenteeism records will be checked for that) - will not be at the same school for the course of the study (1 year)

	- not meeting the inclusion criteria **Inclusion criteria Module 5:** - Students of the classes included in the study in each included school in Palestine **Exclusion criteria Module 5:** Refusal to participate by the student or his/her parents **Inclusion criteria Module 6:** For students: - Students of the intervention schools - Students from the 50-student sample selected in each included school For teachers: - Aged ≥ 18 years old - Permanent employees in the school - Teaching one of the classes included in the intervention **Exclusion criteria Module 6:** Not providing signed consent form and/or oral assent **Inclusion criteria Module 7:** - The participant needs to be: a) a stakeholder within the community, state, region or country of the intervention whose position is related in any way to WASH in schools b) working in one of the intervention schools. They can be teachers, hygiene technicians or in a leading position of the school. c) Minimum age of 18 years **Exclusion criteria Module 7:** Refusals to participate
Measurements and Procedures	Different methods across modules will be used to achieve the objectives of this project. These modules will include qualitative and quantitative data approaches in order to enable a triangulation of the overall project results. The following modules will be used in the cRCT and the overall project: (i) Module 1: A combined RANAS and wellbeing survey, (ii) Module 2: Structured handwashing observations, (iii) Module 3: Microbiological analysis of hand rinse samples, (iv) Module 4: Diary approach for pre-defined health outcomes and absenteeism incidence, (v) Module 5: personal, physical, and social contextual factor survey, (vi) Module 6:FGDs and (vii) Module 7: Key informant interviews (KIIs). Endpoints of Modules 1-3 will be assessed at baseline, at follow-up and endline of the cRCT. Module 4 will be used to collect data longitudinally over the course of 12 months. Module 5 will be assessed at baseline and only in Palestine, Module 6 and 7 will be used in the middle of the intervention phase in the intervention groups.
Number of Participants with Rationale (if no Power Analysis conducted)	The sample size calculation yielded that 13 schools are needed per arm with 50 students per school. With political instability and other factors which might lead to a loss of follow-up, we have 7 schools as backup schools. This will lead to 26 schools in total with a total number of 1300 students. The number of students participating in different modules will differ due to the capacity limitation of assessing the 50 students included in each school. For module 1, only 25 students of the 50 students included in the study in each school. For module 2, the 50 students included in the study in each school will be targeted for assessment using this module. For Module 3, 12 students out of the 25 randomly selected students to be targeted with RANAS and well-being survey will be targeted for assessment using this module.

	Module 4 follows the sample size calculation of the cRCT design, hence 50 students from each of the 26 schools will be monitored. For Module 5, all students in the included classes in each school in Palestine will be delivered a survey to be self-reported by their parents. For Module 6, 10 FGDs (including students) and 5 FGDs (including teachers) will be administered and for Module 7, 10-20 interviews.
Study Duration	14 months
Study Schedule	For Nigeria: May 2023 of First-Participant-In July 2024 of Last-Participant-Out For Palestine: March 2023 of First-Participant-In May 2024 of Last-Participant-Out
Investigator(s)	Prof. Dr. Mirko Winkler Swiss Tropical and Public Health Institute Kreuzstrasse 2 4132 Allschwil Phone: +41612848339 mirko.winkler@unibas.ch PhD candidate (research assistant) under supervision of Prof Dr. Mirko Winkler: Yaman Abuzahra Swiss Tropical and Public Health Institute Kreuzstrasse 2 4132 Allschwil, Switzerland yaman.abuzahra@swisstph.ch Zainab Abdulkarim Terre des hommes Nigeria No. 46 Talba Road, By Horama Specialist Hospital Junction off Allamin Daggash Road Maiduguri, Borno State, Nigeria Phone: 08065541603,08029218162 Zainab.abdulkarim@tdh.ch Issa Younan Project coordinator Cesvi Palestine Ata Al-Zir Street 15, Beit Hanina, Jerusalem, Palestine +970592859990 technical_supervisor@cesvioverseas.org Rena Salzmann Junior Programme Officer Skat Foundation Benevolpark, St.Leonhard-Strasse 45 9000 St.Gallen, Switzerland +41 71 227 07 99 rena.salzmann@skat-foundation.ch
Study Centre(s)	Nigeria and Palestine
Statistical Analysis incl. Power Analysis	The number of clusters (schools) and students per school were calculated using the software R with a power simulation of 80% developed by Dr Jan Hattendorf. The Intraclass Correlation Coefficient (ICC) was assumed at 0.2. The simulation assumed a prevalence of handwashing occurrence before eating during the time of observation (3 hours) taking place over one day of 20% in control vs 45% in intervention schools after 1 year from the

	baseline. Based on this assumption, 13 schools are needed per arm with 50 students per school. The baseline data will be reported descriptively. The imbalance at baseline between trial arms will be assessed in terms of clinical importance rather than in terms of statistical significance. The intervention effect will be estimated with logistic mixed effect regression to adjust for potential correlation within schools. For the primary analysis, the model will include only the outcome (handwashing occurrence before eating during the time of observation (3 hours) taking place over one day and assessed at the endline) and the intervention as a predictor and school as a random effect. Further analyses will include known confounders and variables imbalanced at baseline. All analyses will use the available case population. No imputation of missing data will be done because loss to follow-up is usually small to moderate in school-based studies.
Ethical consideration	This project will be carried out in accordance with the research plan outlined in this protocol and with principles enunciated in the current version of the Declaration of Helsinki / Essentials of Good Epidemiological Practice issued by Public Health Switzerland (EGEP) / ISO EN 14155 / CIOMS International Ethical Guidelines for epidemiological studies 2009 as well as all national legal requirements and guidelines as applicable. This protocol will be reviewed by the Ethikkommission Nordwest- und Zentralschweiz (EKNZ, Ethics Committee of Northern and Central Switzerland) and also be reviewed and approved by the National Health Research Ethics Committee. This trial will be registered at the U.S. National Library of Medicine under ttps://www.clinicaltrials.gov.

2 BACKGROUND INFORMATION

2.1 Global public health relevance of water and hygiene

Water insecurity has been a primary underlying determinant of global health disparities (Stevenson *et al.* 2012). In recognition of the importance of achieving universal access to safe water and hygiene services, one of the 17 Sustainable Development Goals (SDGs) established by the United Nations in 2015 is dedicated to "ensure availability and sustainable management of water and sanitation for all" (SDG 6) (UN 2015). Improving access to water and hygiene contributes to enhancing several essential aspects of life and achieving other SDGs (UN 2006), such as contributing to ending poverty (SDG 1) and hunger (SDG 2), promoting health and well-being for all at all ages (SDG 3) and empowering women (SDG 5) (UN 2015).

Despite considerable progress in increasing access to safe water and sanitation, billions of people –primarily located in low- and middle-income countries (LMICs) (Guardiola *et al.* 2014; Kangmennaang and Elliott 2021) – still lack access to essential water and hygiene services required for a healthy life and well-being (WHO and UNICEF 2019). More specifically, a third of the world's population does not have access to safe drinking water and 40% lack access to basic handwashing facilities with water and soap (WHO and UNICEF 2019). Consequently, billions of people are exposed to increased risk of water and hygiene-related diseases, with an estimated 2 million people, predominantly children, dying each year from diarrheal diseases alone (WHO and UNICEF 2019). A problem that is aggravated among children under five in LMICs by the exposure to drought that is likely to increase due to climate change (Wang *et al.* 2022).

2.1.1 Access to water and hygiene for disease prevention

Studies have shown that proper handwashing with soap reduces the transmission of diarrheal diseases by 30% to 48% (Bloomfield *et al.* 2007; Ejemot *et al.* 2008; Freeman *et al.* 2014; Prüss-Ustün *et al.* 2019) and respiratory diseases by 21% (Aiello *et al.* 2008; Warren-Gash *et al.* 2013). Furthermore, proper hand hygiene plays an important role in controlling the spread of epidemics such as cholera (Taylor *et al.* 2015; Ngwa *et al.* 2020), ebola (Wolfe *et al.* 2017), hepatitis E (Teshale *et al.* 2010), SARS (Fung and Cairncross 2006), and shigellosis (Khan 1982). Also, during the current COVID-19 pandemic, handwashing with soap has received unprecedented attention for being the most effective measure to reduce the transmission of the infection. For example, Beale et al. (2021) showed that improved hand hygiene reduced the likelihood of contracting a COVID-19 infection by 36% (Beale *et al.* 2021). Indeed, if there is anything that the COVID-19 pandemic has reinforced, it is that increasing access to sustainable sanitation and handwashing facilities is more important than ever.

2.1.2 Access to water and hygiene for the well-being

In addition to contributing to the transmission of infectious diseases – as demonstrated by the COVID-19 pandemic (WHO 2020)–, there is substantial evidence of the adverse effects that a lack of access to water and hygiene can have on people's psychological and physical status, social relationships and interactions with the environment (Guardiola *et al.* 2014). Yet we do not fully understand how water stressors impact people's overall satisfaction with their lives (Rosinger and Young 2020; Kangmennaang and Elliott 2021).

2.1.3 Access to water and hygiene in humanitarian settings

In humanitarian settings[1], providing access to improved water[2] and hygiene is often particularly challenging (Ersel 2015). For example, because of the ongoing crisis in Palestine due to the long-standing Israeli occupation that started in 1967 (OCHA 2021), more than 1.6 million Palestinians in West Bank and Gaza have limited access to their basic WASH needs including access to water, sanitation and hygiene services (OCHA 2021). In Area C, which represents 60% of the West Bank and is under Israeli administrative and military control (UN HRC 2021), Palestinians have no access to their natural water resources due to the activity of Israeli settlements illegally established in this area (UN HRC 2021). Indeed, Israeli settlers diverted water resources and seized water wells under the cover of the military (UN HRC 2013; B'Tselem 2017). Consequently, the decreased amount of available water to Palestinians leads to a decrease in access to sanitation and hygiene. In such conditions, the need for sustainable interventions to support WASH services significantly increases, and the well-being benefit of according interventions is expectedly very high. However, the complex and multidimensional nature of the crisis in Palestine makes tackling WASH vulnerability even more challenging.
Another setting where access to WASH services frequently falls short of minimum requirements is refugee camps where limited water resources along with high population density result in restricted availability of drinking and use water for refugees (UNHCR 2022). For example, in the Mafa displacement camp in Borno state, Nigeria, WASH access for Internally Displaced People (IDP) is very limited, with waiting times for being provided with water supplies often ranging between three to six hours (UN 2020). This situation became even more challenging when parts of the camp were destroyed twice by fire in 2018 and 2022 (the Guardian and the Tdh). In addition, the escalating tensions between the jihadist group Boko Haram and the Nigerian army triggered an increase in the number of IDPs, making drinking and cooking a higher priority than providing access to sanitation and handwashing.

On one hand, challenges in accessing water and WASH services at large are causing a wide range of adverse health conditions in humanitarian contexts. On the other hand, the promotion of access to water and hand hygiene has proven to significantly reduce the transmission of infectious diseases (Pittet 2017), including COVID-19 (UN 2020). Hence, for promoting health and well-being in a humanitarian context there is a strong need to promote and evaluate interventions that aim to improve access to water and hand hygiene.

2.2 Hand hygiene in schools

The latest data reported by the WHO and UNICEF Joint Monitoring Programme for Water Supply, Sanitation and Hygiene (JMP) revealed that 42% of schools (affecting 802 million schoolchildren) lack access to handwashing facilities, basic hygiene and water supply systems (UNICEF and WHO 2022). To achieve universal coverage of basic hygiene in schools by 2030, a 5-fold increase in the current progress rates is needed (UNICEF and WHO 2022).
33% of the schools lacking access to handwashing facilities are found in the Least Developed Countries (LDCs)[3] and over 50% of them are found in fragile contexts[4]. Also, according to the WHO, the staff in the schools in LDCs and fragile contexts often lack the knowledge and

[1] Humanitarian setting is where an event or series of events, usually over a large area, poses a serious threat to the health, safety, security, or well-being of a community or other large population which requires large amounts of external assistance, resources, and a multi-sectoral response involving a wide range of international humanitarian organizations to ensure people's survival, care, and protection (UNICEF 2022)

[2] Improved water is protected water from outside contamination, specifically from faecal contamination (WHO 2022)

[3] Least developed countries (LDCs) are *"low-income countries confronting severe structural impediments to sustainable development. They are highly vulnerable to economic and environmental shocks and have low levels of human assets"* (un.org).

[4] Fragile contexts are "*contexts where there is an accumulation and combination of risks as a result of context-specific underlying causes combined with insufficient coping capacity of the state, system and/or communities to manage, absorb or mitigate those risks.*" (unicef.org)

capacity of managing WASH services adequately (UNICEF and WHO 2022). Therefore, it is crucial to concentrate efforts on providing adequate WASH services in such contexts by targeting school staff and students with sustainable interventions that improve their level of water access and hand hygiene behaviour, also given that children in these schools likely also have no or very limited hand hygiene resources at home and in their family environment. The Hands4Health (H4H) project primarily addresses such contexts where WASH services are inadequate, and large investments for improvement of infrastructure are unlikely in the near future. This is the case in many conflict areas, refugee and internally displaced population camps, informal settlements and remote rural areas with poor or failed institutional structures. Within this project schools located in such contexts in Nigeria and Palestine are targeted to implement the H4H Multi-Component Intervention (MCI).

2.3 The hands4health project

This project is funded by the Swiss Development Cooperation (SDC) (https://hands4health.dev/) and aims to increase hygiene in schools without any direct access to water in the context of humanitarian crises. The project has a strong focus on the Sustainable Development Goal (SDG) 6, clean water and sanitation. In addition, the SDG 1 (no poverty), SDG 3 (good health and wellbeing), SDG 4 (quality education), SDG 5 (gender equality), SDG 10 (reduced inequalities), and SDG 11 (sustainable cities and communities) are targeted (Pradhan *et al.* 2017). The project is led by 10 partners from academia, non-governmental organizations (NGOs), and the private sector. To increase the level of hygiene, an intervention package consisting of (i) a handwashing station called Gravit'eau (only in Nigeria), (ii) rehabilitation of WASH infrastructure (only in Palestine) (iii) a behaviour change intervention from Ranas Ltd., a spin-off company of the Swiss Federal Institute of Aquatic Science and Technology (Eawag), (iv) training for monitoring residual chlorine in water storage by Fachhochschule Nordwestschweiz (FHNW) (only for Palestine), (v) capacity development on O&M and overall management by Fachhochschule Nordwestschweiz (FHNW), and (vi) the management of WASH infrastructure at facilities, including water storage, water distribution, handwashing and sanitation by FHNW. The Gravit'eau is designed by Gravit`eau Association, and evaluated by FHNW previously together with Gravit`eau and will be tested by the FHNW with filters supplied from the company Martin Systems. The Ecole Polythechnique Fédérale de Lausanne (EPFL) will test different greywater disinfection methods. The behavioural change intervention will be designed and lead by Ranas Ltd. The NGOs Terre des hommes (Tdh) and Cesvi will support the intervention and all data collection with local teams and expertise in Nigeria and Palestine, respectively. The Swiss Tropical and Public Health Institute (Swiss TPH) will lead the efficacy assessment of the project. The Palestinian Polytechnic University (PPU) and the University of Maiduguri (UNIMAID) have leading roles in the technology evaluation and user-centered design for local context; impact evaluation; water quality analysis, data collection and analysis; and quality control. Skat Foundation will coordinate the development of a systematic approach to facilitate handwashing in institutional settings, as well as develop an overall Theory of Change (ToC) for the intervention and a stakeholder engagement strategy. The ToC process, which will be continued throughout the project duration, and the systematic approach are directly related – both processes provide feedback to each other. One of the main results will be a Theory of Action (ToA), which will help the field and project teams to plan and implement their activities in a strategic and targeted way. The ToC aims to help local teams and the researchers to understand how the local WASH system works in schools in Nigeria and Palestine, and to identify the interplay of actors and factors that shape the overall system dynamic.

2.3.1 Gravit'eau handwashing station

Gravit'eau is a handwashing station which recycles water with gravity (Gravit'eau 2022). The station does not need to be connected to an electricity source as it is activated by a foot pump. The design of the station is adaptable to the context of use and can hold up to 90 litres of water. The used water is collected and treated using gravity in a grease trap and by gravity-

driven membrane filtration. The membrane module contains an ultrafiltration membrane that removes pathogenic microorganisms. In schools, chlorine can be added as a second barrier. The then pathogen-free water is stored in a storage tank until its next use (http://www.graviteau.ch). To keep an acceptable water quality also in terms of colour, the water needs to be replaced about once a month and the filter needs to be replaced every five to eight years (Gravit'eau 2022).

In contrast to pre-existing handwashing stations using a bucket with a tap, Gravit'eau can save time and water resources by reducing the frequency of refilling the water tank from once a day to once a month. Consequently, more water can be saved for other purposes such as drinking or sanitation and the time efforts of the staff of the facility are reduced as well. Moreover, the station is built by local contractors using local materials, which enhances durability, facilitates maintenance and offers an opportunity to adapt the design to the needs of the facility and the context (like the size of the doors in the facility, inside or outside, etc.). So far, the station has been tested in a laboratory at FHNW, at a German Music Festival, in mobile health clinics in Palestine, in child-friendly spaces and schools in Nigeria, and in health clinics in Mali. However, these tests did not involve long-term data collection. In order to scale up the use of Gravit'eau, the station needs to be tested in the field for at least nine months to take into account daily use, seasonal water shortages, local adaptation, and climate conditions.

2.3.2 Rehabilitation of WASH infrastructures

At an early stage of the H4H project, it became clear that the implementation of the Gravit'eau devices in Palestinian schools is not culturally acceptable. The Palestinian Ministry of Education refused to use recycled water due to social and administrative obstacles. Alternatively, different rehabilitation works will take place in the schools according to each school need. These activities include, construction of drinking stations, rehabilitation of toilets and handwashing stations, installing water-saving taps and installing soap dispensers at drinking and handwashing stations.

2.3.3 Behavioural change intervention

The risks, attitudes, norms, abilities, and self-regulation (RANAS) model was developed based on theories from environmental and health psychology in order to systematically change behaviour (Figure 1). To change behaviour effectively, the underlying behavioural factors need to be addressed and changed (Mosler and Contzen 2016). According to the developers of the RANAS approach, "[RANAS] is an easily applied method for measuring behavioural factors, assessing their relevance for the target behaviour, designing tailored strategies that change the target behaviour, and measuring the effectiveness of these" (Mosler and Contzen, 2016: 5) (Mosler and Contzen 2016). The RANAS approach consists of four phases: (i) identification of potential behavioural factors through an explorative phase with qualitative data collection tools; (ii) measurement of these factors with a questionnaire and determination of the relevant factors steering the behaviour (i.e. hand washing with soap) through statistical analyses; (iii) selection of behaviour change techniques from a standardized catalogue of Behaviour Change Techniques and development of campaign activities; and (iv) implementation and evaluation of these behaviour change activities. The RANAS approach is always tailored to the local context and takes into account a wide range of potential behavioural barriers and motivators based on the RANAS model, namely risk factors, attitude factors, norm factors, ability factors and self-regulation factors as well as social, physical and personal context. Ranas trains local "Ranas experts" and supports them in developing a behaviour change activity catalogue adapted to the local schools' context, which will be thoroughly piloted before implementation. The RANAS approach has been applied successfully in a variety of settings

to change hygiene behaviour (Contzen *et al.* 2015, Gamma *et al.* 2017, Friedrich *et el.* 2018, Chidziwisano *et al.* 2019).

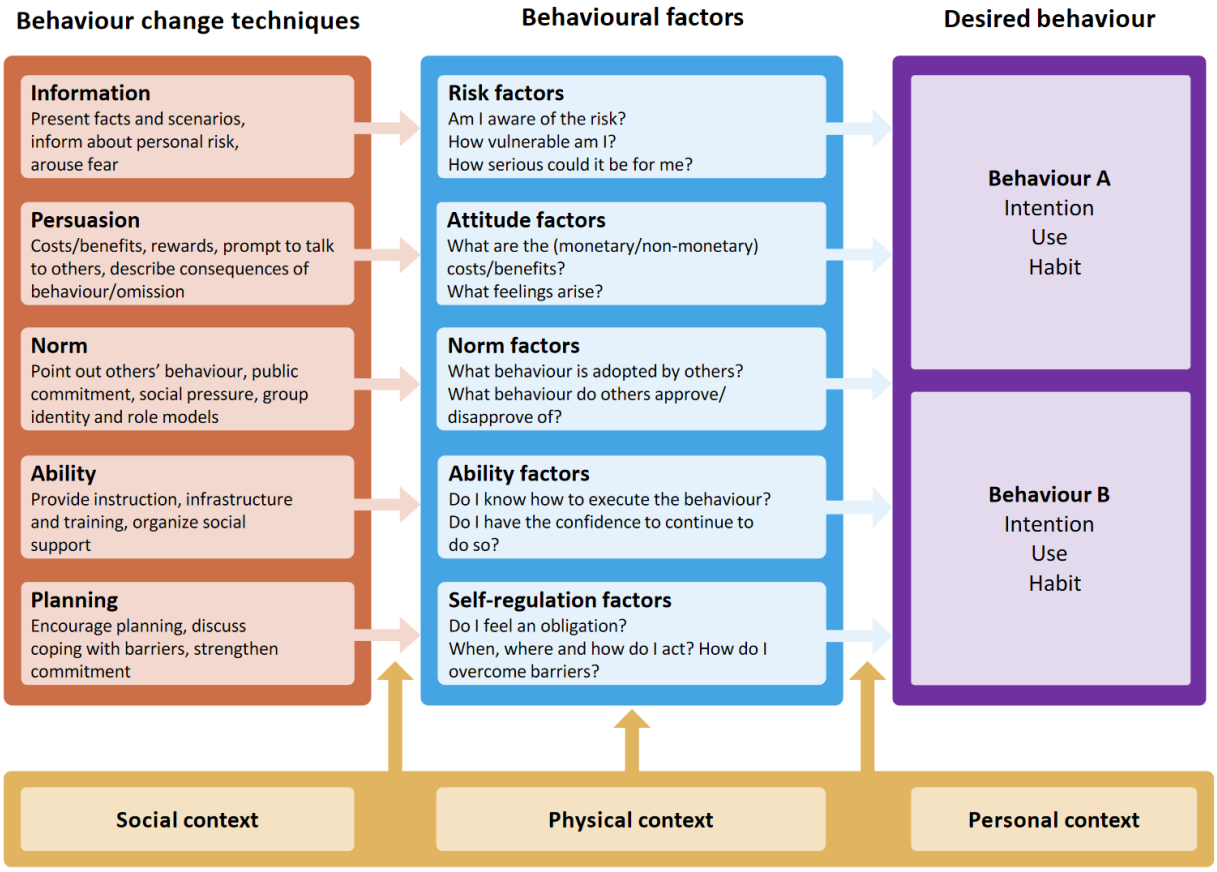


Figure 1: RANAS model for behaviour change (Mosler and Contzen 2016)

2.3.4 Capacity development and training for monitoring residual chlorine in water storage

The Ministry of Health (MoH) in Palestine chlorinates the water in the main reservoirs before being distributed to houses and community institutions, including the schools. However, water could be contaminated while being transferred to or stored in schools. The schools usually send water samples to test for any physical and biological contamination once per semester. No further testing of the water takes place in schools due to the shortage of the staff of the Ministry of Health who can perform the testing. Additionally, the schools are missing the tools needed for monitoring processes. There is a need for regular water testing to monitor the concentration of residual chlorine. The staff needs to be able to ensure water is chlorinated regularly and properly and requires:

- hardware to monitor chlorine to be available
- knowledge of how to measure concentrations

FHNW supports the Cesvi team to choose the equipment to monitor chlorine concentration. During the training of trainers workshop they will train the teams and representatives of the Ministry of Education on these aspects and discuss with them the possibility of training the staff of the schools and supporting the overall maintenance of infrastructure to introduce controlled monitoring of residual chlorine. The Cesvi team will train the staff of the schools afterwards and review the management systems to ensure the chlorine testing is functional and there is quality control and monitoring in place

2.3.5 The management of WASH infrastructure at schools

The support in the management of the WASH system in each school will be carried out according to improvement plans resulting from the discussion with School WASH Committee. In this context, regular check of infrastructure, support from, a trained person, and equipped with proper tools under the supervision of the School WASH committee could be delivered. The regular checks aim to provide preventive maintenance to WASH infrastructures and/or support the capacity development of the institutions' staff in daily management. The goal is to treat small issues before they grow in magnitude.

According to the local context and needs, appropriate activities might be the following:

- Providing routine maintenance of WASH infrastructure and equipment
- Providing regular follow-up to the staff in the proper operation of WASH infrastructure, basic maintenance, water treatment methods, and responding to additional training requests from staff as needed
- Build the capacity of school principals on budget planning for the maintenance of WASH equipment
- Providing timely repairs (e.g. plumbing fixtures and water supplies, latrines, handwashing stations)
- Providing regular maintenance to Gravit'eau stations
- Inspecting and servicing latrines, tanks, sinks, handwashing stations
- Conducting water quality tests to ensure drinking water standards are met
- Reporting on WASH functionality to the relevant stakeholders
- Conducting assessment and identification of further needs

3 OBJECTIVES AND PURPOSE

3.1 Study rationale and objectives

3.1.1 Study rationale

Due to the critical role hand hygiene plays in disease transmission, promoting hand hygiene became a mainstay in national infection prevention and control (ICP) strategies (WHO 2015). However, systematic reviews of hygiene promotion interventions showed mixed results on the effectiveness of these interventions for improving hand hygiene and identified, at the same time, a range of challenges, including the need to identify different factors responsible for hand hygiene (Naikoba and Hayward 2001; Wilson *et al.* 2011; Luangasanatip *et al.* 2014; De Buck *et al.* 2017; Mbakaya *et al.* 2017; Slekiene and Mosler 2017; Watson *et al.* 2017; Martin *et al.* 2018). Furthermore, there is a lack of information to draw conclusions about the factors affecting hand hygiene in humanitarian settings (White *et al.* 2020).

Behavioural determinants of hand hygiene can also be affected by different contextual factors (Mosler 2012), especially during a humanitarian crisis (Contzen and Mosler 2013). It remains plausible that major disruptions of someone's social life, psychological or physical status, such as thos experienced during crises or emergencies could lead to changes in the handwashing behaviour determinants (Mosler 2012; De Buck *et al.* 2017). Therefore, it remains crucial for the effectiveness and also the local adaptation of hand hygiene promotion interventions to include a "soft" component that addresses a range of behavioural determinants of handwashing along with different contextual factors that can influence the behaviour.

Furthermore, there is a lack of understanding of the many pathways and mechanisms through which insufficient access to water and hygiene services impacts the overall well-being and associated dimensions (Kangmennaang and Elliott 2021). Overall, only a few tools exist to conceptualise and quantitatively measure the association between water access and overall

health and well-being (Kangmennaang and Elliott 2021). This represents a limitation in comprehensively measuring and evaluating the broad health and well-being effects of WASH interventions (Kangmennaang and Elliott 2021).

Knowledge about the effectiveness of hand hygiene campaigns in the context of humanitarian emergencies is extremely scarce due to the lack of baseline data and monitoring and evaluation activities (Vujcic *et al.* 2014, Als *et al.* 2020). In conflict settings, hand hygiene is mostly being investigated in community settings, but not in schools where infections can easily spread (Als *et al.* 2020, Domini *et al.* 2020). In addition, data mainly relies on self-reporting and can therefore rarely be triangulated. Moreover, information about barriers and motivators of handwashing campaigns in emergency settings is scarce (Vujcic *et al.* 2014). Finally, data on handwashing interventions in complex emergencies is rarely shared publicly and therefore is not being used to inform other handwashing campaigns (Vujcic *et al.* 2014).
The Gravit'eau handwashing station is a promising invention to increase access to water in settings suffering water scarcity and humanitarian crises. However, its impacts on health determinants and outcomes of its users have to date never been assessed in a real-world setting over long time periods (Gravit'eau 2022). For scaling up the use of Gravit'eau, scientific evidence about its impact and potential barriers to implementation are much needed.

3.1.2 Primary objective

Evaluate the effects of the H4H MCI on hand hygiene of primary school students in Nigeria and Palestine. In this objective, the following research question will be addressed.

RQ 1.1 Can a quantifiable change in hand hygiene be detected due to the intervention?

3.1.3 Secondary objectives

Additionally to the primary objective, the H4H project aims to address the following secondary objectives and research questions:

1) **Evaluate the effects of the H4H MCI on the well-being of primary school students in Nigeria and Palestine**

   RQ 1.1 Can a quantifiable change in well-being be detected due to the intervention?

2) **Assess the effect of the H4H MCI package on hygiene-related risks, attitudes, norms, abilities and self-regulation (RANAS) behavioural factors of primary school students**

   RQ 2.1: Can the H4H intervention package be associated with a change in hygiene-related RANAS behavioural factors of primary school students?
   RQ 2.2: Which factors promote the uptake of the intervention?

3) **Explore the associations of personal, physical and social contextual factors with hand hygiene and well-being of primary school students in Palestine**

   RQ 4.1 Which factors related to personal, social or physical contexts are independently or jointly associated with hand hygiene and well-being?

4) **Explore the perceived impacts of the H4H MCI package on the health and well-being of primary school students**

   RQ 4.1 What are the students' and teachers' perceived impacts of the H4H MCI on their hand hygiene, health and other issues?

RQ 4.2 What are the students' and teachers' perceived obstacles and challenges for scaling up the H4H MCI in the schools?
RQ 4.3 What are the proposed solutions for addressing these challenges?

3.1.4 Explorative objectives

1) **Assess the effect of the H4H MCI package on hygiene-related health outcomes and absenteeism incidence of primary school students in Nigeria and Palestine**

RQ 1.1 What are the trends in students' absenteeism resulting from hygiene-related infections over time in the two arms of the trial?
RQ 1.2 What are the trends in hand hygiene-related health outcomes over time in the two arms of the trial?

3.2 Scientific justification of study population

The schools' teachers and students are at increased risk for disease transmission, particularly during disease outbreaks (Wolf *et al.* 2018). Improved water access and hand hygiene are essential to maintaining a hygienic environment for controlling infectious disease transmission in schools (Robinson 2001). In addition, schools are well positioned in principle to implement equitable and sustainable health-related behaviour changes that track from childhood to adulthood (Moore *et al.* 2015).
In Nigeria, it was reported that 70% of the schools lack hygiene services and 43% of them lack sanitation services (UNICEF & WHO 2022). A recent study also showed that there is a significant WASH inequality between private and public schools in Nigeria (Wada *et al.* 2022). None of the public schools included in the study (5 schools) provided any sanitation or hygiene services whereas the other 5 private schools provided both services. The authors of the study indicated that there is a need for sustainable WASH interventions engaging local community stakeholders to facilitate the narrowing of existing inequalities (Wada *et al.* 2022).
The overcrowding conditions in the schools where the average number of students per elementary class ranged from 51 to101, along with the humanitarian crisis urge the need for targeting these schools with sustainable interventions promoting WASH services and hand hygiene. The targeted schools in H4H project lie around Maiduguri, the capital and the largest city of Borno State in north-eastern Nigeria. The humanitarian needs are increasing in all locations in Borno state due to escalating crisis between the Boko Haram group and the Nigerian army, however, many places like the Mafa refugee camp are hardly or not accessible due to deteriorated security. The focus has been shifted to the schools around Maiduguri, which are likely to remain accessible.
In a different fragile setting, a long-lasting military occupation in Palestine created an unstable and coercive humanitarian environment that left a lot of schools, specifically in Area C, deprived of basic water and hygiene services. According to the JMP report, basic hygiene services are available in only 21% of the schools in Palestine (UNICEF and WHO 2022). There are 3 types of schools in Palestine; public, private and UNRWA[5]-administered. The schools lie in Area C are either public or under the administration of UNRWA. The latter type lies in refugee camps that are completely under the supervision of UNRWA. The project targets public schools in remote and rural areas in Area C that are most in need for WASH services improvement. The average number of students per elementary class in these schools is about 30. Usually, in such schools any improvement to WASH sector is challenging due to restrictions on infrastructure rehabilitation imposed by the Israeli military occupation.
The H4H project primarily addresses such contexts where WASH services are inadequate, and large investments for the improvement of infrastructure are unlikely in the near future. This is the case in many conflict areas, refugee and internally displaced population camps,

[5] UNRWA is The United Nations Relief and Works Agency for Palestine Refugees in the Near East

informal settlements and remote rural areas with poor or failed institutional structures. Within this project schools located in such contexts are targeted to implement the H4H MCI.
Tdh and Cesvi have established offices in Nigeria and Palestine supporting health and WASH interventions in schools. Tdh and Cesvi collaborate closely with local authorities and the most relevant stakeholders who expressed their support for this project.

4 STUDY DESIGN

The overall project will follow a multi-center cluster-randomized controlled trial (cRCT) design (Figure 2). Prior to this study, a group of schools in the study's target areas were surveyed by the Tdh (in Nigeria) and Cesvi (in Palestine) using the Facility Evaluation Tool for WASH in Schools (FACET WINS) which is a monitoring tool for WASH delivery services in schools. From these schools a subsample was identified which fulfils certain inclusion criteria (for the inclusion criteria see chapter 5.2 Inclusion criteria).

This subsample was handed over to the local Tdh and Cesvi collaborators who carefully assessed the security situation around the schools. The Tdh and Cesvi collaborators then selected 26 facilities per country, which are most probable to still be accessible for data collection within the next year. These 26 schools will then be allocated to the two arms (intervention vs. control) with covariate constrained stratified randomization using computer-generated randomization code provided by a statistician not involved in any field activities. The intervention arm will receive the full intervention package (handwashing station, behavioural change intervention, capacity development, and management support). The control arm will receive nothing for the duration of the intervention (12 months). Afterwards, they will receive the same intervention package with potential improvements identified in the former intervention group.

In the selected schools, 50 eligible students from each school will be selected from one or two classes within the age group (10-12 years) using random sampling. If the school has at least one class that has ≥ 50 students within the target age group, the sample will be selected from that class, otherwise, the sample can be selected from two classes. For module 1, only 25 students of the 50 students included in the study in each school will be involved. For module 2, the 50 students included in the study in each school will be targeted for assessment using this module. For Module 3, 12 students out of the 25 students targeted with assessment using module 1 will be targeted for assessment using this module.
Module 4 follows the sample size calculation of the cRCT design, hence 50 students from each of the 24 schools will be monitored. For module 5 which is only restricted to students from Palestine, the same sampling plan of the cRCT will be used, and the sample size will be the one foreseen to fulfil the main study objectives. For Module 6, 10 FGDs (including students) and 5 FGDs (including teachers) will be administered and for Module 7, 10-20 interviews.

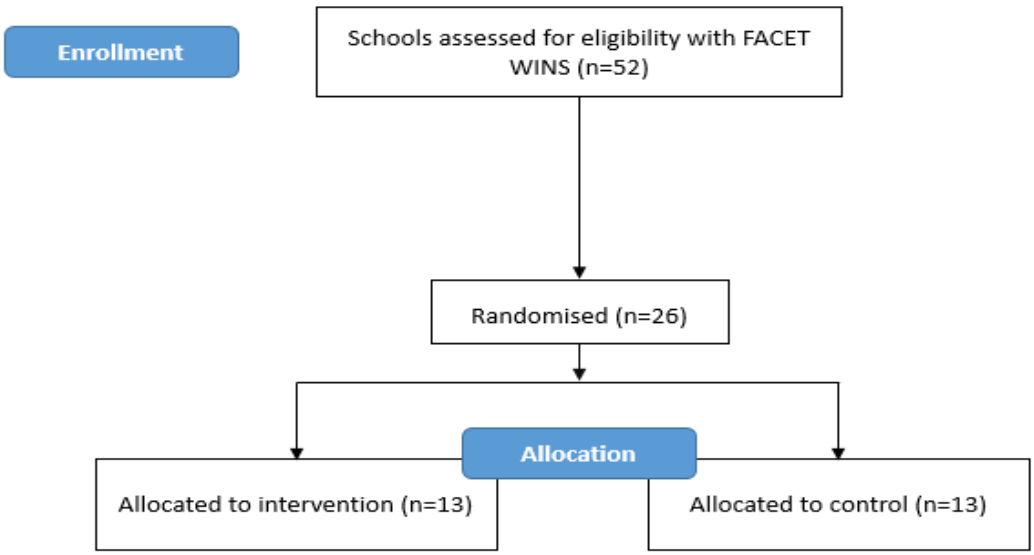


Figure 2: Consort flow diagram of the schools selection for the H4H cRCT in Nigeria

The methods to achieve the different objectives of this project are summarized in Table 1. These modules will include qualitative and quantitative data approaches in order to enable a triangulation of the overall project results. The following modules will be used in the cRCT and the overall project: (i) Module 1: Combined RANAS and well-being survey, (ii) Module 2: Structured handwashing observations, (iii) Module 3: Microbiological analysis of hand rinse samples, (iv) Module 4: Diary approach for health outcomes and absenteeism, (v) Module 5: personal, physical and social contextual factors survey (vi) Module 6: Focus Group Discussions (FGDs) and (vii) Module 7: Key informant interviews (KIIs).

Table 1: Overview of different project modules and analysis by objective

Module	Objective	Analysis
Module 1: Combined RANAS and well-being survey	PO: Evaluate the effects of the H4H MCI on hand hygiene of primary school students in Nigeria and Palestine SO1: Evaluate the effects of the H4H MCI on the well-being of primary school students in Nigeria and Palestine SO2: Assess the effect of the H4H MCI on hygiene-related RANAS behavioural factors of primary school students	- Descriptive statistics and multiple random effect regression models
Module 2: Structured handwashing observations	PO: Evaluate the effects of the H4H MCI on hand hygiene of primary school students in Nigeria and Palestine	- Descriptive statistics, multiple linear regression models and logistic regression models
Module 3: Microbiological analysis of hand rinse samples	PO: Evaluate the effects of the H4H MCI on hand hygiene of primary school students in Nigeria and Palestine	- Analysis of *E. coli* and total coliforms - Descriptive statistics, multiple linear regression models
Module 4: Diary approach for pre-defined health outcomes and absenteeism	EO1: Evaluate the effects of H4H MCI on health outcomes and absenteeism	- Descriptive statistics
Module 5: personal, physical and social contextual factors survey	SO3: Explore the associations of personal, physical and social contextual factors with hand hygiene and well-being of primary school students in Palestine	- Descriptive statistics, multivariate regression models
Module 6: Focus Group Discussions	SO4: Explore the perceived impacts of the H4H MCI on the health and well-being of primary school students	- Framework methodology
Module 7: Key informant interviews	SO4: Explore the perceived impacts of the H4H MCI package on the health and well-being of primary school students	- Framework methodology

Local collaborators from Tdh and Cesvi and the regional Ministries of Education (MoE) were involved from the study's kick-off meeting onwards and are regularly being consulted in bi-weekly meetings and additional ToC workshops led by Skat Foundation. The data collection methods for each module will be described in further detail:

Module 1: Combined RANAS and well-being survey: The survey will be developed through the RANAS approach and will not only include attitude and belief questions, but also target the underlying psychological factors postulated by the RANAS model that are important precursors for effective behaviour change (Mosler and Contzen 2016). If needed, this survey will be enriched with additional questions to assess the knowledge and self-reported handwashing practices of the participants. The well-being of the students will be assessed in the survey using the KINDL tool (Ravens-Sieberer and Bullinger 1998). It is a tool designed to measure health-related quality of life in children and adolescents by looking into different domains of well-being (e.g. physical, mental and school) (Ravens-Sieberer and Bullinger 1998). The perceived sufficiency and safety of the water supply, satisfaction with the available infrastructure for handwashing, and obstacles to water access will be also assessed. The survey will be administered to primary school students three times in total; as a baseline survey before the intervention package, about three months after the intervention and about a year after the baseline survey with the software Open Data Kit (ODK) Central (version 2022.3.1) on Android tablets. Informed consent forms will be obtained from the participants' guardians before the day of data collection. In addition, oral assent will also be obtained from the participants at the beginning of the interview for filling out the survey.

Module 2: Structured handwashing observations: Structured handwashing observations are perceived as a gold standard method to assess handwashing behaviour in schools (Pickering *et al.* 2013; Caruso *et al.* 2014; Dreibelbis *et al.* 2016; La Con *et al.* 2017; Parkinson *et al.* 2018). Data from Module 1 and the observations can later be combined through a unique ID of the study participants. The observations will be administered with students three times at the same time points as the survey in Module 1. To be able to assess individual behaviours and link them to data collected using other tools, all eligible students in the classes selected for the study will be assigned coloured badges with their unique IDs. Students will be informed that they are randomly assigned the colours. However, the data collector will agree with the school teachers on a specific colour to be assigned for the 50 selected students for the study. The observation will start at 9:00 am (60 minutes before the breakfast break) and end at 12:00 pm (90 minutes after the break). The data collector will pilot the observation process before the intervention and in coordination with the school staff.

The occurrence of handwashing with soap will be observed for each of the two critical handwashing events (after using the toilet and before eating) for each included student. The occurrence of handwashing before eating (our primary outcome) is an opportunity that could be observed once for all students when break time starts. The break time included in the observation period is the first break for all students during a school day, and all of them use it for eating their brunch (as confirmed by the local teams). No matter where the station is they are expected to come and wash their hands before eating. For observing the occurrence of the other critical event and if the station was not located next to toilets, we would have two observers; one is next to toilets and the other one is next to the stations. Both would observe and then compare their results. The observations will result in a dichotomous measure, i.e. if the handwashing with soap for each critical event occurred or not. However, there will be choices like "was not visible" or "soap or water was not available" to take into consideration the complicated conditions in the field.

If the opportunity for handwashing before eating was not possible for all students, an alternative scenario is proposed. In the class before the break, students will be engaged for 30 minutes in painting activity. At the end of the activity and as a reward, students will be provided with a popcorn snack and will be given free time of 15 minutes so they can eat together the snack. They need to use their hands for eating the popcorn, so, they are expected to wash their hands before eating it. They will also be told they can go outside the classroom if they want so they would be left with the choice to wash their hands before eating if they want. During that time, one observer will be standing close to the handwashing stations (or water points before installing the Gravt'eau) and recording all the students who take the

opportunity and wash their hands before eating and any other handwashing opportunity, e.g. after using the toilet. The observation will continue during the break time (45 minutes) so as to cover all opportunities for handwashing before eating for students who opted not to eat the snack and want to have lunch during the break. Students will be asked to keep the badges until the end of the activity. Other handwashing opportunities will be also recorded.
Also, if it was feasible the steps of handwashing will be observed for the students who wash their hands.
Consent for observation will be obtained at a school level, from the principal of the school, as well as from the parents.

Module 3: Microbiological analysis of hand rinse samples: Hand rinse samples of students will be collected after administering the survey with a modified glove juice method as described by Pickering et al. 2010. First, the enumerators will visually assess the cleanliness of the participant's hands with an observation form prompting for visible dirt in different areas of the hands, such as the thumb and under the fingernails (Contzen *et al.* 2015, Pickering *et al.* 2010 (b)).

For the hand rinse sample collection, the enumerators will have to wear sterile gloves. The participant's randomly selected hand will be inserted into a 69-oz Whirl-Pak bag (NASCO Corp., Fort Atkinson, WI) filled with 350 mL of clean water. Then, the participant has to shake her/his hand in the water and rub her/his thumb and fingers together for 15 seconds. Afterwards, the enumerator will massage the participant's hand through the bag for another 15 seconds. The participant will be provided with a paper towel to dry the hand, once it is retrieved from the bag (Pickering *et al.* 2010 (b)). Afterwards, the procedure will be repeated with the other hand.

The Whirl-Pak bags containing the samples will be kept on ice in an isolation box and processed within 4 hours of sampling (Pickering *et al.* 2010 (b)). Membrane filtration will be used to detect colony-forming units (CFUs) of *E.Coli* and total coliforms. In a field laboratory, the content of the bags will be passed through a 47-mm-diameter 0.45 µm cellulose filter. The filter paper will then be placed on growth media and incubated at 35°C ± 0.5°C for a duration of 24 hours for *E.Coli* and total coliforms (Pickering *et al.* 2010 (b)). We plan to filter 100 mL per bag to detect CFUs of *E.Coli* and total coliforms. The exact amount of mL will be established during piloting as the volume used is dependent on the degree of bacterial contamination on the hands. Compact dry plates will be used for the detection of *E.coli* and total coliforms.

The lower detection limit of CFUs will be calculated by dividing 1 CFU/plate by the filtrate volume and then multiplying it with the total Whirl-Pak volume of 350 mL. The upper detection limit will be calculated by dividing 500 CFUs/plate by the filtrate volume and then multiplying it with the Whirl-Pak volume. For the statistical analysis, the CFUs per hand will be normalized and $\log_{10}$ transformed (Pickering *et al.* 2010 (b)).

Module 4: Diary approach for pre-defined hygiene-related health outcomes and absenteeism incidence: Longitudinal data on hygiene-related health outcomes and absenteeism will be collected over the study course (12 months) in both arms of the study. The main outcome of this objective is students' hygiene-related absenteeism. Absenteeism is hygiene-related if the student suffered from diarrhoea, respiratory tract infections, helminth infections, head lice, trachoma and skin infections. For the outcome of this objective an electronic/paper diary will be prepared by the PhD and used in each school by one of the teachers on a daily basis to report the absenteeism of included students in each cluster along with the reason for their absenteeism (pre-defined health outcomes). To adjust for the cluster design effect, we will calculate the rates of hygiene-related absenteeism separately for each medical reason for each school. This will be carried out by dividing the number of episodes of hygiene-related absenteeism for each medical reason by the number of student-weeks. The

answer will then be multiplied by 100 to obtain rates per 100 student-weeks and will be presented using descriptive statistics.

Module 5: personal, physical and social contextual factors survey: Handwashing behaviour and well-being of school children are not only influenced by the level of water access and psychosocial behavioural factors but also depend on culture- and context-related factors. The exceptional stressors forced by the prolonged military occupation in Palestine result in difficult personal, social and physical conditions which lead to disruption in different aspects of life beyond the school environment. The analysis of all possible determinants of hand hygiene behaviour and well-being at baseline before the start of the intervention will provide a better understanding of factors that potentially modify the effectiveness of an intervention and may need consideration for maximising effectiveness on hygiene and well-being when implementing larger-scale WASH interventions in the Palestinian context.
The study design will be baseline cross-sectional. This objective will be fulfilled through the baseline assessment conducted before randomising the recruited schools in Palestine into the two arms of the study. The assessment will be carried out through a survey that is self-reported by the parents of the students in the selected classes for the study. The survey will include questions related to the availability of hygiene services at the household level, evaluation of parents' hygiene knowledge and behaviour, and assessment of their child's hygiene behaviour as reported by them.

Module 6: Focus Group Discussions: The FGD is a rapid and resource-efficient method of gathering information since all the target participants and the researcher are readily available at the same study site (Mack *et al.* 2005; Nyumba *et al.* 2018). There is no need to collect participants from different environments and prepare them in advance, rather, they will be met in their usual studying environment which also helps not to introduce their expectations and biases, including strategic group bias (Nyumba *et al.* 2018). Also, the concentrated nature of the FGD avails a large quantity of data in much less time usually needed to collect an equivalent number of interviews (Nyumba *et al.* 2018).
10 gender-separated FGDs will take place in the included schools in the intervention arm; 5 FGDs for each gender in autumn 2023. However, the saturation factor[6] will be considered when conducting the discussions in the field. Each group will include students of the same age of the age group target (10-12) to avoid any domination of older students if the groups include different age groups. Using separate groups for boys and girls will help ensure meaningful feedback since children may feel shy speaking in front of each other and usually there is an increase in teasing among children at the age of 10 (Dzino-Silajdzic 2018). It is important for them to feel comfortable speaking their minds freely and not feel shy, embarrassed or worried someone will make fun of them (Dzino-Silajdzic 2018). Each FGD will be composed of 5-8 selected students. The selection of the students will be consulted with the school administration, however, selected students need to represent each participating class in the intervention arm of the trial.
Additionally, there will be 5 FGDs composed of 5-8 teachers from included schools in the intervention arm. The teachers invited to participate in the FGDs should be permanent employees in the school and teach the classes included in the intervention.
Data will be collected by a small local team with experience in qualitative data collection and if the security situation allows, the PhD student would join the team. The team will be composed of at least a moderator and a note taker who is trained prior to data collection by the PhD student. A field research journal will be used throughout the data collection to take structured notes and observations of the FGDs. The discussions will be tape-recorded and then transcribed in the local language and translated into English for further analysis.

[6] Saturation is reached when answers of participants start repeating and no new information can be gained through additional FGDs.

Field notes, observation notes and focus group transcripts will be analysed using the framework method with the software MaxQDA (VERBI Software, Marburg, Germany) or NVivo (QSR International, Melbourne, Australia) (Gale *et al.* 2013).

Module 7: Key informant interviews: The key informant interviews target stakeholders in the Ministry of Education, school committee and leaders of the community to help solicit a different kind of information that is deeper and more detailed about the nature of the problems and recommended solutions. These insights help in the triangulation of data and could not be gained through the FGDs as the group dynamic may not allow for asking probing and in-depth questions (Kumar 1989). Also, having stakeholders in the FGD may prevent other participants from voicing their opinions (Mack *et al.* 2005). The KIIs will take place in autumn 2023.

Interviewers will receive the same training as for the Focus Group Discussions. The interviews will be audio recorded and then transcribed into the local language and translated into English for further analysis. In some instances, interviews may be carried out remotely (online) from Switzerland, in English, if it is appropriate. They will be audio recorded, transcribed, and translated if necessary for further analysis.
As the FGD transcripts, the interviews will be analysed using the framework method with the software MaxQDA (VERBI Software, Marburg, Germany) or NVivo (QSR International, Melbourne, Australia) (Gale *et al.* 2013).

4.1 Primary endpoint

The main aim of the intervention is to improve hand hygiene. So, hand hygiene will be assessed in this study by assessing the occurrence, frequency and technique of handwashing behaviour using different tools. We will operationalise our target behaviour in this study as handwashing with water and soap at two critical events: (i) after using the toilet and (ii) before eating. However, the primary outcome in this study is the occurrence of handwashing with water and soap before eating during 3-hours observation for one day. It is selected as the primary outcome since it could be objectively assessed for all included students during the break whether because they have the opportunity since they eat their brunch during the break, or because they will eat a snack provided to them on the day of data collection.

4.2 Secondary endpoints

The most important secondary endpoints are:

A) Good handwashing practice defined as students who wash their hands with water and soap after using the toilet assessed by structured handwashing observation
B) Self-reported handwashing practice at the two critical events (before eating and after using the toilet) including occurrence, frequency and technique of handwashing behaviour will be assessed using the survey on a Likert scale ranging from almost never to almost always.
C) The well-being of the students will be assessed using the KINDL tool (Ravens-Sieberer and Bullinger 1998).
D) The log-transformed number of total coliforms and E.coli CFUs per hand before handwashing.
E) Hygiene-related health outcomes and absenteeism. The health outcomes will be reassessed with local experts to assure feasibility before the start of the intervention.

Covariates are assessed with RANAS variables as exposure variables and good handwashing practice as outcome variable. Covariates for estimating the total effect of RANAS on good

handwashing practice are age, education, sex, socio-economic status, handwashing practices, and the water infrastructure of the schools.

4.3 Measures to minimize bias

Different biases might arise in this project. To prevent selection bias and confounding in the two study arms, we will use stratified block randomization to balance the two arms with respect to important baseline characteristics. Due to the nature of the intervention, neither the participants, nor the data collectors of the study, nor the statistician can be blinded. However, to reduce selective counting of CFUs on the hand-rinse samples, the lab workers assessing the number of CFUs will be blinded.

In Module 1, the RANAS and well-being survey, we expect a recall bias and a desirability bias. To minimize the recall bias, participants will not be asked to report any events which have taken place longer than a week ago. To reduce the desirability bias, the people administering the survey will not label themselves clearly as Tdh or Cesvi staff members, because local people know that Tdh and Cesvi often delivers humanitarian aid in the region and might want to impress the Tdh and Cesvi teams. Additionally, to reduce any study personnel bias, the data collectors will all receive a training in advance. Their ID will be recorded in the survey form in order to be able to conduct quality control.

For Modules 1 to 3, data collectors have to upload the completed surveys every night, once they have a stable internet connection. All of the surveys will have the data collector's ID. The PhD student from Swiss TPH will control every second day how long the data collectors took to complete a survey, if certain answers are always the same for specific data collectors and the amount of missing data per survey. In addition, the GPS location of the tablet will be recorded to make sure that the data collection actually took place at the predefined location. These components will be correlated in the statistical software R (version 4.1.3) to test for significant differences between data collectors. In case a data collector delivers significantly different results which are not deemed realistic by the Swiss TPH study team and the local main correspondents of Tdh and Cesvi, the staff will be asked to comply with predefined rules once. If they still do not comply afterwards, they will be replaced. Faulty data from these staff members can then not be used any more for analysing the results of the H4H project. Modules 1-3 will be repeated three months after the intervention and nine months after the intervention.

For Module 2, the handwashing observations, a Hawthorne effect is to be expected (the tendency of individuals to modify their behaviour due to their awareness they are being observed (McCambridge *et al.* 2014)). To minimise the Hawthorne effect, students will not be informed of being observed and the data collector will not get closer to the student being observed than needed to observe soap use. However, there is a possible source of bias resulting from the possibility of children connecting having someone close to the handwashing station with the intervention.
In Module 3, the microbiological analysis, a study personnel bias could influence the quality of the hand rinse samples and the accuracy of counting the CFUs. To be aware of differences between the data collectors, their ID will be stored during the sample collection on ODK. The number of CFUs per plate will be correlated with the people who collected the data to see if there are any significant differences between data collectors. The people counting the number of CFUs will be blinded and therefore do not know if the sample comes from the intervention or the control group. Additionally, every 10^{th} sample will be duplicated during the data collection and the CFUs on every 10^{th} plate will need to be counted additionally by another staff member as quality control.

To enhance the reliability of the outcomes from modules (1-3), it is proposed that each school be visited by two teams over two consecutive days for data collection. The first team of observers will conduct observations and collect hand rinse samples, while the second team of

interviewers will visit the same school on the following day to administer the RANAS and well-being survey to the students (as shown in Figure 3). This approach is recommended to avoid any potential positive impact on handwashing behaviour that may result from survey questions if students were surveyed first. Additionally, it will ensure that students' responses to the survey are not influenced as they will not be aware of being observed on the first day.

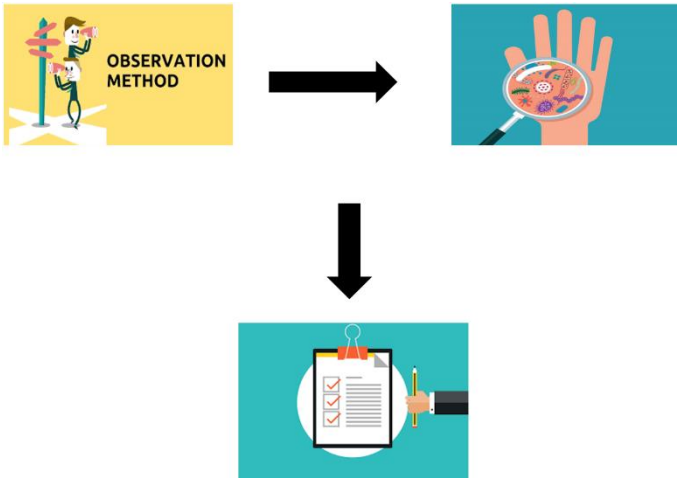


Figure 3: Flow-chart of data collection activities at baseline, follow-up and endline of the project depicting observations, the RANAS questionnaire and the hand-rinse samples.

In Module 4, students' hygiene-related health outcomes and absenteeism will be reported by one of the teachers in each school. To facilitate the process, a system of automatic weekly messages will be generated to remind teachers of filling out the absenteeism survey, and one of the tdh and Cesvi staff will follow and check their submissions on the ODK centre. However, different biases might arise. Depending on how dutifully the teachers report and on the severity of the health outcomes, a detection bias might occur. We will test for this bias by correlating the school with the proportion of reported days of absenteeism and health outcomes over a year. In order to intervene in case such differences exist, we will correlate the data in each quarter of the study year as a form of quality control. In addition, a form of selection bias can happen if a certain group of students falsely report a medical reason as an excuse for their absence on certain days. For example, a student might report his/her reason for being absent is being sick with any of the predefined hygiene-related health outcomes. To minimise such biases, the form of absenteeism that the teachers use contains a question about the availability of a medical report. If there is no medical report and the teacher still questions the reliability of the reason for the absence, they are asked to depend on their experience and knowledge to judge if the student's excuse is false or not. We are aware that this module is suboptimal due to the difficulty to confirm the reasons for the students' absenteeism. However, this is only part of an exploratory objective. We still think that if differences can be observed between the two intervention arms, this module is of high importance as it would demonstrate the significance of the H4H MCI in schools. If these differences can be demonstrated on a local level, motivating local schools and the Ministry of Education for future handwashing interventions might become easier.

To assure the quality and functioning of the Gravit'eau handwashing stations, regular integrity tests and water quality tests will show if the systems are still functional and capable to remove the bacteria. *E.coli* tests of handwashing water will show if there is any recontamination or any integrity problem. In case there is a problem, we will provide an alternative solution (e.g. bucket with soap) and rehabilitate the handwashing systems or dose chlorine into handwashing systems and repeat the test.

In case a school has 25% higher negative health outcomes than the average of all schools, the regional Ministry of Education and Ministry of Health will be consulted to check if this is usual. If not, the study will have to be stopped in this school.

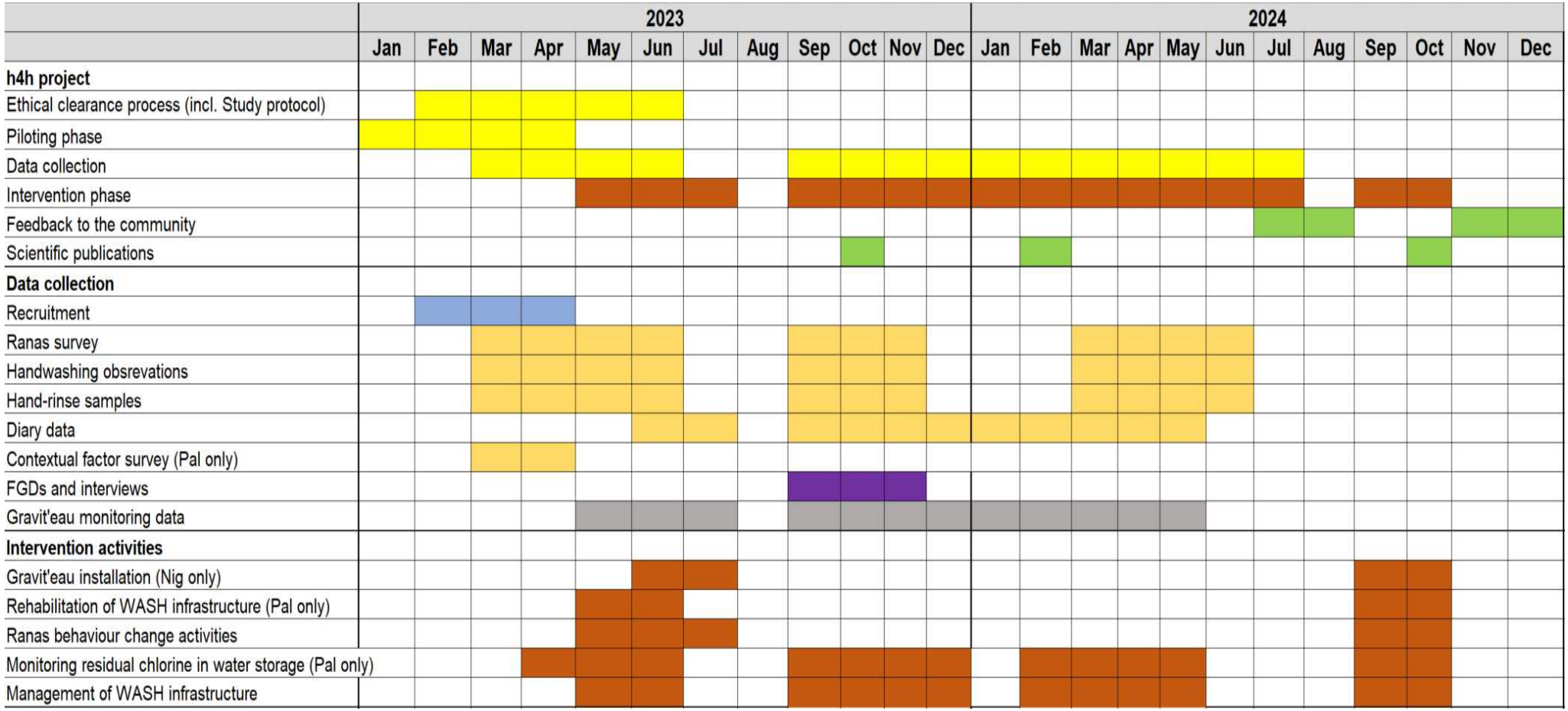
4.4 Study duration and duration of participant's participation

Students will be regularly approached for data collection. As mentioned above, the data collection phase will start with observation for 50 students selected for the study, and is then followed by collecting hand rinse samples for 12 of them. On the second day of data collection, 25 out of the 50 students will be interviewed with RANAS and well-being survey. The observations will extend for 3 hours and the hand-rinse samples will take about 10 minutes including oral assent. The questionnaire will take a maximum of 20-25 minutes including oral assent as well. The contextual factor survey is expected to take 8-10 minutes from one of the parents to answer.

Entering the students' absenteeism and the pre-defined health outcomes in the diary over the course of the year will not take much time of the teachers. To write down an event of absenteeism will take the teacher about one minute per student.

Finally, some of the students and teachers of the 13 intervention schools will be asked to take part in FGDs or interviews. This should not take them longer than one hour. KIIs with stakeholders outside of the schools will also be limited to one hour.

4.4.1 Schedule of events



4.5 Amendments

All of the different modules will be piloted in pilot schools of the study regions and adapted to local needs and circumstances.
Substantial changes to the project set-up; the protocol and relevant project documents will be submitted to all of the Ethics Committees for approval according to the local EC guidelines.

4.6 Withdrawal and discontinuation

Participants may stop their participation at any time and withdraw their consent. However, data obtained prior to participant's withdrawal will be included in analysis to ensure the validity of the study. Data of withdrawn participants are fully anonymised once analysis is completed. Local staff is recruited and employed by Tdh and Cesvi and has to follow the terms and conditions of the local Tdh and Cesvi offices which are written in their work contract.
The overall H4H project or specific project sites can be discontinued due to several reasons by the project leader, such as:

- Ethical concerns (e.g. non-acceptance of proposed technical solutions)
- Insufficient participant recruitment
- Natural hazards (e.g. heavy floods, earthquakes)
- Damage and vandalism of infrastructure, technical failure of interventions
- Alternative interventions and projects at the same facilities not coordinated with us
- Limited access by Tdh or Cesvi staff due to any reason out of their control including pandemics, natural hazards or deterioration of security situation
- Political constraints restricting access to the schools or the project implementation

4.7 End of project

The biological material from the microbiological analysis will be destroyed upon completion of data analysis. Health-related data will be stored in an anonymized form for a minimum of 10 years at a password-protected server of Swiss TPH. Photos, videos and recordings from the project will be stored on a password-protected server of Swiss TPH, tdh, Cesvi or FHNW. If photos or videos contain pictures of people, they will be asked for their oral consent.

5 SELECTION OF STUDY PARTICIPANTS

5.1 Recruitment

Recruitment will differ according to the study modules. Participants will always be recruited within the clusters (primary schools). For the RANAS and well-being survey (Module 1) only 25 students randomly selected out of the 50 students randomly selected from the classes included in the intervention in each school will be targeted. For the handwashing observations (Module 2) and the diary approach (Module 4) the 50 students randomly selected from the classes included in the intervention in each school will be targeted. For the hand-rinse samples (Module 3) only 12 students randomly selected out of the 25 students randomly selected to be targeted with the RANAS and well-being survey will be targeted. For the contextual factor survey (Module 5), all students in the the classes included in the intervention in each school will be invited to participate by delivering a survey to be reported by one of their parents about the contextual factors that could affect hygiene practice of the students.

For the FGDs (Module 6), 10 gender-separated FGDs will take place in the included schools in the intervention arm; 5 FGDs for each gender. However, the saturation factor will be considered when conducting the discussions in the field. Each FGD will be composed of 5-8 selected students and they will be asked for their consent to participate. The selection of the students will be consulted with the school administration, however, selected students need to represent each participating class in the intervention arm of the trial.

Additionally, there will be 5 FGDs composed of 5-8 teachers from included schools in the intervention arm. The teachers invited to participate in the FGDs should be permanent employees in the school and teach one of the classes included in the intervention.

For the KIIs (Module 7), local partners will be consulted on who they see as a suitable stakeholder for an interview. The sampling procedure will therefore be a purposeful sampling. Interviewees will be contacted by the local partners. Interviews will be held until saturation is reached.

5.2 Inclusion criteria

Study participants will be primary school students of schools selected to be included in this study. Schools were selected based on accessibility for the study teams, not having a water source directly connected to the building of the school, having ≤ 7000 students. 50 students within the age of 10-12 years old from one or two classes (depending on the number of students in classes) of the 5th-7th grades will be included in the study from each included school. However, due to the large size of the schools and high number of classes in Nigeria, the 50 students will be selected from two classes of the 5th-7th grades close to where the handwashing stations (Gravit'eau) will be positioned. The 50 selected students will be targeted with the handwashing observation (Module 2) and followed for their hygiene-related health outcomes and absenteeism during the course of the study (Module 4), while 25 of them will be targeted with RANAS and well-being survey (Module 1) and 12 of them will be targeted with collecting their hand-rinse samples (Module 3). Students in the selected classes in each school will be delivered a survey to be self-reported by one of their parents about contextual factors that could affect hygiene practice of students (Module 5 in Palestine only).

Inclusion criteria Modules 1-4: students must fulfil all the inclusion criteria:
- Primary school students aged 10-12 years attending included schools
- Students must be in the same school for the course of the study (1 year).

Inclusion criteria Module 5: students must fulfil all the inclusion criteria:
- Students of the classes included in the study in each included school in Palestine

Inclusion criteria Module 6:
- Students of the intervention schools
- Students need to represent each included class in the intervention.

The teachers invited to participate in the FGDs should be
- Aged ≥ 18 years old
- Permanent employees in the school
- Teaching one of the classes included in the intervention

Inclusion criteria Module 7:
- The participant needs to be:
  a) a stakeholder within the community, state, or region of the intervention whose position is related in any way to WASH in schools
  b) working in one of the intervention schools. They can be hygiene technicians, teachers, school's principal, or in a leading position in the school.
  c) Aged ≥ 18 years old

5.3 Exclusion criteria

Exclusion criteria Modules 1-4: included students must not fulfil any of the following exclusion criteria:
- Refusal to participate by not providing signed consent and assent forms
- Having any medical condition that prevents them from washing their hands
- Having unexplained intermittent attendance in school (school teachers will be consulted and the school's absenteeism records will be checked for that)

- Not being at the same school for the course of the study (1 year)

Exclusion criteria Module 5: Refusal to participate by the student or his/her parents.

Exclusion criteria Module 6: Refusals to participate.

Exclusion criteria Module 7: Refusals to participate

5.4 Criteria for discontinuation of study

5.4.1 Discontinuation of individual participants

A participant can be discontinued from the study for the following reasons:

1. Withdrawal of informed consent
2. Moving from the included school to another school
3. Long-lasting absence of at least 6 months
4. Death
5. Inaccessibility of the school due to a high risk security situation

6 STATISTICS

6.1 Hypothesis

6.1.1 Primary hypothesis

The primary hypothesis stems from the research question: Does the H4H MCI make a difference in the hand hygiene of primary school students in Nigeria and Palestine?

$H_{1.1}$= There is a difference in hand hygiene between the intervention and control groups of primary school students in Nigeria and Palestine.

$H_{0.1}$= There is no difference in hand hygiene between the intervention and control groups of primary school students in Nigeria and Palestine.

6.1.2 Secondary hypotheses

Depending on the secondary objective, different secondary hypotheses were formed:

$H_{1.1}$= There is a difference in well-being between the intervention and control groups of primary school students in Nigeria and Palestine.

$H_{0.1}$= There is no difference in well-being between the intervention and control groups of primary school students in Nigeria and Palestine.

$H_{1.2}$= There is a difference between hygiene-related RANAS variables between the intervention and control groups of primary school students in Nigeria and Palestine.

$H_{0.2}$= There is no difference between hygiene-related RANAS variables between the intervention and control groups of primary school students in Nigeria and Palestine.

$H_{1.3}$= There is association between personal, physical and social contextual factors and hand hygiene and the well-being of primary school students in Palestine.

$H_{0.3}$= There is no association between personal, physical and social contextual factors and hand hygiene and the well-being of primary school students in Palestine.

$H_{1.e}$= There is a difference in hygiene-related health outcomes and absenteeism between the intervention and control groups of primary school students in Nigeria and Palestine.

$H_{0.e}$= There is no difference in hygiene-related health outcomes and absenteeism between the intervention and control groups of primary school students in Nigeria and Palestine.

6.2 Determination of sample size

The number of clusters (schools) and students per school was assessed by simulations using the software R aiming for a power of 80% at the 95% confidence level. The Intraclass Correlation Coefficient (ICC) was assumed at 0.2. The simulation assumed a prevalence of handwashing occurrence before eating during the time of observation (3 hours) taking place over one day of 20% in control vs 45% in intervention schools after 1 year from the baseline. Based on this assumption, 13 schools are needed per arm with 50 students per school. However, the number of students assessed for different modules will differ due to the capacity limitation of assessing the 50 students included in each school.

For Module 1, only 25 students randomly selected out of the 50 students randomly selected from the classes included in the intervention in each school will be targeted. For Modules 2 and 4 the 50

students randomly selected from the one or two classes included in the intervention in each school will be targeted. For Module 3 only 12 students randomly selected out of the 25 students involved in module 1 in each school will be targeted. For Module 5, all students in the the classes included in the intervention in each school will be invited to participate by delivering a survey to be reported by one of their parents. For Module 6, 10 gender-separated FGDs will take place in the included schools in the intervention arm; 5 FGDs for each gender. In addition, 5 FGDs targeting teachers will be conducted. For Module 7, 10-20 interviews will be conducted.

6.3 Description of statistical methods

Baseline characteristics will be summarized using descriptive statistics. The difference in the observed proportion of washing hands before eating between two study arms at follow-up will be investigated using logistic mixed effect regression to adjust for potential correlation within schools. In the primary analysis only the intervention will be included as predictor and school as a random effect.

6.3.1 Datasets to be analysed, analysis populations

For the primary analysis we will use the available case population of primary school students which will be analysed according to the intention-to-treat principles.

6.3.1.1 Primary Analysis

Module 1: RANAS and well-being survey: The data will be summarized using descriptive statistics. Associations of RANAS behavioural factors with good handwashing practices and students' well-being with the other outcome variables from RANAS behavioural factors will be estimated using random effect linear regression modelling and random effect logistic regression modelling. Missing data will clearly be reported but not imputed.

Module 2: Structured handwashing observations: To quantify the intervention effect logistic regression with binomial distribution with random intercepts for schools models will be applied.

Module 3: Microbiological analysis of hand rinse samples: For investigating factors associated to *E.coli* and total coliform prevalence on primary school students' hands, random effect linear regression models will be applied.

Module 4: Diary approach for hygiene-related health outcomes and absenteeism: The rates of hygiene-related absenteeism will be calculated separately for each health outcome per school. To quantify the intervention effect on hygiene-related health outcomes and absenteeism, random effect linear regression modelling will be used.

Module 5: Personal, physical and social contextual factor survey: The independent and joint association of personal, physical and social contextual characteristics with handwashing behaviour, and well-being (total score and domain-specific scores) will be analysed in the context of multivariate regression models that apply a variable-selection procedure that takes interactions into consideration to not miss those factors where the association depends on the presence of one or more additional variables. To assess personal profiles consisting of a combination of factors, a clustering approach for factors with a statistically significant association with handwashing or well-being will be applied.

Modules 6 and 7, FGDs and KIIs: FGDs and KIIs will be audio recorded, transcribed, and translated if necessary for further analysis. The local perception of the success and sustainability of the H4H intervention will be analysed using the framework method with the software MaxQDA (VERBI Software, Marburg, Germany) or NVivo (QSR International, Melbourne, Australia) (48).

6.3.1.2 Secondary Analyses

In a secondary analysis the models will be adjusted for known confounder and additional predictors imbalanced at baseline.

6.4 Handling of missing data

No imputation of missing data will be done because loss to follow-up is usually small to moderate in school-based studies.

7 DESCRIPTION OF DATA MANAGEMENT

7.1 Specification of source documents

The source documents needed in this study are listed in the table below:

Source document	Where can the source document be found / way of collection	Storage
List of schools	Produced during the pilot phase of the H4H project using the Facility Evaluation Tool for WASH in Schools (FACET WINS)	Electronic storage in password-protected secure server at Swiss Tropical and Public Health Institute and FHNW
Informed Consent Forms (ICFs)	Will be signed at the school and scanned	Destruction of paper form and storage of the scan on the password-protected secure server of Terre des hommes/Cesvi.
Electronic case report form (CRF) for the RANAS and well-being survey	Will be collected with a password-protected tablet with automatic deletion of data after transmission to server	Electronic storage in password-protected secure server at Swiss Tropical and Public Health Institute, Switzerland and during the study duration on a password-protected Swiss TPH Laptop of the local study coordinator.
Paper and electronic CRF for the structured handwashing observations	Data will be collected on paper and then the data have to be entered into a password-protected tablet with automatic deletion of data after transmission to server	The paper collected will be kept in a locked cabinet at the tdh/Cesvi offices. Electronic storage in password-protected secure server at Swiss Tropical and Public Health Institute, Switzerland and during the study duration on a password-protected Swiss TPH Laptop of the local study coordinator.
Electronic CRF for the microbiological hand-rinse samples	Will be collected with a password-protected tablet with automatic deletion of data after transmission to server	Electronic storage in password-protected secure server at Swiss Tropical and Public Health Institute, Switzerland and during the study duration on a password-protected Tdh/Cesvi Laptop of the person responsible for data entry.
Paper and electronic CRF for FGDs	Will be read and moderated to the participants during the FGDs	Electronic storage in password-protected secure server at Swiss Tropical and Public Health Institute, Switzerland and during the study duration on a password-protected Swiss TPH Laptop of the local study coordinator. Paper CRF will be disposed at the study centre after the FGD.
Electronic and paper output of FGDs	Audio recordings of the FGD will be transcribed in a word file on a password-	Electronic storage in a password-protected secure server at Swiss Tropical and Public Health Institute, Switzerland

	protected Tdh/Cesvi Laptop. FGD notes from the field journal will be collected	and during the study duration on a password-protected Tdh/Cesvi Laptop of the person responsible for the transcription. The written paper notes will be stored in a locked cabinet at the study site.
Electronic and paper output of KIIs	Audio recordings of the KII will be transcribed in a word file on a password-protected Tdh/Cesvi Laptop.	Electronic storage in password-protected secure server at Swiss Tropical and Public Health Institute, Switzerland and during the study duration on a password-protected Tdh/Cesvi Laptop of the person responsible for transcription. Any written paper notes will be stored in a locked cabinet at the study site.
Participant identification list	Will be obtained during the baseline survey	Locked cabinet at study site (only accessible by field coordinator and the staff conducting the follow-up surveys)
Paper or electronic CRF for spot checks of Gravit'eaus	Data entry into a table on paper or an excel sheet at the study site. If previously collected on paper, the data will have to be entered into an excel sheet in a second step.	Electronic storage in password-protected secure server at Swiss Tropical and Public Health Institute, Switzerland and during the study duration on a password-protected Tdh Laptop of the person responsible for data collection. If the data is being collected on paper, storage is in a locked cabinet at the study site.
Paper CRF for the diary approach of hygiene-related health outcome and absenteeism reporting	Data will be collected continuously in the schools by the teachers on monthly sheets of paper. Once a month, Tdh/Cesvi staff then collects these paper sheets.	First in a locked cabinet at the school and after pick up by Tdh/Cesvi in a locked cabinet at the Tdh/Cesvi office.
Electronic CRF for the diary approach of hygiene-related health outcome and absenteeism reporting	Data will be entered from the paper CRF to an excel sheet	Electronic storage in password-protected secure server at Swiss Tropical and Public Health Institute, Switzerland and during the study duration on a password-protected Tdh/Cesvi Laptop of the person responsible for data entry.
Paper CRF for the personal, physical and social contextual factor survey	Data will be collected on paper by students' parents and the papers will be then sent to the school by their children. Cesvi staff will then collect these papers form the school official	First in a locked cabinet at the school and after pick up by Cesvi in a locked cabinet at the Cesvi office.

Electronic CRF for the personal, physical and social contextual factor survey	Data will be entered from the paper into a password-protected tablet with automatic deletion of data after transmission to server	Electronic storage in password-protected secure server at Swiss Tropical and Public Health Institute, Switzerland and during the study duration on a password-protected Cesvi Laptop of the person responsible for data entry.

7.2 Data recording and source data

Informed consent, the participant identification, the structured observation CRF, the spot check CRFs, and the contextual factor CRF, and the health outcome and absenteeism diary CRFs will be obtained on paper forms. All the forms will then be stored in a locked cabinet at the study site at the Tdh/Cesvi office. Participant identification will not be kept in the same cabinet as the rest of the forms.

The survey CRF will be collected electronically using password-protected tablets from Swiss TPH and Open Data Kit (ODK) software (University of Washington, Seattle WA, USA). The content on the tablets will be deleted automatically after the transmission to the server at Swiss TPH, Switzerland. The server is secure and password protected. The list of schools, electronic CRFs for the handwashing observations, the microbiological analysis, the health outcomes and absenteeism diary, the contextual factor survey and the transcripts of the FGDS and KIIs will be stored on the same password protected Swiss TPH server. Microsoft Word and Excel documents will have a clear and uniform name structure including the place of data collection, date and version number to guarantee data traceability. The process of constantly updating data collection will not involve changes to the CRFs' version number or date. Any updates to these documents must be approved by the ethics committee before implementation.

7.3 Confidentiality and coding

Project data will be handled with uttermost discretion and is only accessible to authorized personnel who require the data to fulfil their duties within the scope of the research project. On the CRFs and other project specific documents, participants are only identified by a unique participant number (ID). The CRFs contain the ID assigned to the participant by the field staff. The name of the participant will be kept in a separate confidential enrolment log that matches identifying codes with the participants' names and residencies during the study. This will only be accessible by the local study coordinator and the people conducting the survey. The document will be stored in the locked cabinet on site and destroyed after the end survey in order to completely anonymize participants.

Biological material (the hand rinse samples) in this project is not identified by participant name but by a unique participant ID. Biological material is appropriately stored in a restricted area in the labs of Tdh and Cesvi offices and only accessible to authorized personnel for a maximum of 48h to be analysed.

7.4 Retention and destruction of study data and biological material

The study data, including audio material, will be stored on the Swiss TPH server and stays there for a time span of 10 years after publication of the research project. The informed consent forms and the participant identification lists will only be kept in paper form and stored at the Tdh and Cesvi offices in Nigeria and Palestine, respectively, for 10 years. After 10 years all electronic data will be deleted and the participant identification list and the informed consent forms will be shredded and disposed of.

Biological material, more specifically the compact dry plates containing hand-rinse samples will be destroyed and disposed after a maximum of 48 hours. The plates have to be disinfected before being disposed of in waste bins. This can either happen by a) putting them into a covered bucket containing 1% bleach solution overnight. The next morning, the bleach solution will be emptied into the waste

water and the plates can be disposed in a plastic bag in any normal waste bin. Or b) the closed plates are placed in a pot of boiling water for a minimum of 10 minutes. After the water cools, it can be emptied into the waste water and the plates can be disposed in a waste bin.

7.5 Data security, access, archiving and back up

An electronic data capture system (EDCS) will be set up which allows to accurately reflect what happened with the study data and the CRFs during the lifetime of the study. This includes a computer-generated time-stamped trail that records all actions performed on the databases (e.g. the individual performing an alteration). For the paper-based CRFs entries and changes need to be signed and dated.

The EDCS contains access restrictions which makes sure that data can only be accessed by qualified and appropriately trained staff who are part of the study delegation, allow for checking the user access against the study delegation log including its documentation, and ensures that the Standard Operating procedures are in place.
All data collected using the study's CRFs is stored electronically on the password protected Swiss TPH server in Switzerland, while the informed consent forms and the participant identification lists will only be kept in paper form and stored at the Tdh and Cesvi offices in Nigeria and Palestine, respectively.
All study data (electronic and paper-based) must be archived for a minimum of 10 years after study termination or premature termination of the study.

8 QUALITY CONTROL AND QUALITY ASSURANCE

8.1 Supervision / Continuous Checks

For the Modules 1 to 3, the electronically collected CRFs will be uploaded to the server every evening. The Swiss TPH PhD student (Yaman Abuzahra) will therefore be able to control the data collection process remotely and intervene if necessary. Additionally, there will be regular debriefings with the data collection staff to react to arising problems or questions. As for the start of Modules 1 to 3, also for Modules 5 and 6, the Swiss TPH PhD student will be based close to the study locations if the security situation permits. Like this daily debriefings about the FGDs can take place and if the security situation permits, the PhD can even join the discussions to observe. In case the PhD student is not able to travel, a minimum of bi-weekly debriefings with the field staff will take place online via Zoom.

8.2 Confidentiality, data protection

All people involved in the study will have access to the study protocol. On request, the protocol can be shared with other parties as well. The participant identification list used for coding is only accessible by the local field coordinator and the people conducting the survey in order to know whom they have to visit. After the end survey, the participant identification list will be destroyed and not accessible to anybody. The datasets and statistical code will be available to everyone involved in the study who needs it in the anonymized form. Data can be published and disseminated because it is anonymized. Also, if there are requests for the dataset or the statistical code from third parties, it can be shared in the anonymized form.

8.3 Translations - Reference language

The reference language of all study documents is English.

The survey questions and important key words of the FGD guide will be translated into Hausa by the Tdh staff in Nigeria and into Arabic by the staff of Cesvi in Palestine. The Swiss TPH staff will then come together with the local Tdh/Cesvi staff for a back translation to English and check if the meaning of the words is still appropriate.

8.4 Storage of biological material and related health data

Water samples and hand-rinse samples will be stored in a refrigerator for a maximum of 48 hours until analysis. If unfiltered water is left from schools, it will be discarded in the drain after resting for 30 minutes with 10mg/L of chlorine. For the analysis, CFUs will be counted and the plates will be photographed. The pictures will be stored in the same way as other health-related data. After counting the CFUs and recording the compact dry plates with pictures, they have to be destroyed immediately to prevent any further growth of potentially harmful bacteria (see chapter 7.4 Rtention and destruction of study data and biological material).

9 ETHICAL CONSIDERATIONS

9.1 Independent Ethics Committee (IEC)

Any protocol amendments, the informed consent, and all other forms of participant information related to the study and any other necessary documents have to be reviewed by an Independent Ethics Committee (IEC). The Ethikkommission Nordwest- und Zentralschweiz (EKNZ) in Switzerland will be asked for approval. The following IECs reviewed the submitted protocol and granted approval in both countries: the National Health Research Ethics Committee (NHREC) in Nigeria, and the Institutional Review Board (IRB) of An-Najah National University in Palestine.

9.2 Risk-benefit ratio

With the H4H intervention, the schools will receive much-needed handwashing infrastructure. An added benefit of Gravit'eau is that it only has to be refilled with water about once a month. This can save the school community precious time at work and water can be saved at the school level to be used as drinking or cleaning water. With the RANAS behaviour change program, the students will receive valuable information on how to maintain good hand hygiene during their stay inside and outside the school. This knowledge together with the available infrastructure will enable the students to better protect themselves against infections and enhance their well-being and satisfaction towards the handwashing structure in their schools. In addition, the students can transfer their knowledge to other students in the school or their families and communities. Finally, if the intervention helps to foster better hygiene at the school level, the school might become more attractive to students and offer a better learning experience.

The control schools will not receive any form of intervention during the year where the intervention package is being tested in the intervention schools. However, after this year, they will also receive an intervention package.

Depending on the Covid-19 situation in the study location, a slightly increased risk of infection arises during the FGDs. However, by conducting the FGDs outside with the use of masks and hand sanitizer and by distancing, this risk will be reduced to a minimum. In addition, the Gravit'eau does not contain water for drinking. Health effects of regular ingestion of Gravit'eau water have so far not been tested. By clearly introducing the Gravit'eau as a handwashing station and by clearly labelling the station with signs that signify "no drinking water", this risk will be reduced. During the piloting phase, the most appropriate and understandable signs will be chosen with the local staff.

To conclude, the benefits of this study for the participants, the schools, and the teachers clearly outweigh the potential risks for study participants. Moreover, the risk of contracting Covid-19 is already a daily risk for the school communities and might even be reduced through better access to handwashing stations.

9.3 Participant information and consent

The Investigator or his/her representative will explain the nature of the study to the participant's guardian and the participants according to the guidelines referred to, and answer all questions regarding this study, prior to obtaining informed consent.

In both countries, the Ministry of Education (MoE) permits written consent from the participant's guardian and oral assent from the children. This approach is adopted to prevent potential confusion among parents/guardians that may arise from seeking written assent. The ethics committees in both countries have granted approval for the consent form to be signed by the participant's guardian, accompanied by oral assent from the children.
In the case of an illiterate participant's guardian, an impartial witness will be called to make sure that the participant's guardian understood the information and agrees. This witness must be independent of the research being conducted and cannot be influenced unfairly by the researchers. For example, a literate relative of the participant's guardian is eligible as an impartial witness. Both, the participant's guardian and the impartial witness must sign the ICF. If the participant's guardian does not have a signature, a fingerprint will be sufficient.

For the handwashing observations, the survey and hand-rinse samples, the participants' guardians will be asked for consent at least two weeks prior to data collection. Their written consent will be sought without letting them know when exactly the observers and enumerators will visit the school.
For the handwashing observation, oral assent of children will be sought retrospectively at the end of the project.

9.4 Participant confidentiality

The Investigators must ensure that the participant's confidentiality will be maintained. Students will be identified on the Case Report Forms with a unique participant ID composed of the initials of the study schools and a serial number (e.g DM12). The Investigators will keep a separate confidential enrolment log that matches identifying codes with the participants' names and residencies.

9.5 Participants requiring particular protection

People in our study regions belong to a vulnerable population because they are living in close proximity to where violent armed groups are active. However, they are capable of judgement and do not apply for any tutelary authority. The H4H project cannot guarantee protection or evacuation in case of a deterioration of the security situation. However, if the security situation would deteriorate so much that the students cannot come to the schools anymore, the study would be stopped in the affected location.

Children under the age of 18 are the study group and they are considered a vulnerable group. To protect the children, their guardian has to sign a written ICF agreeing their child's participation in the study. In addition, the participant has to provide oral assent to participate in the study.
There are no particular risk for the children is expected during any of the study's modules.

9.6 Participant compensation

Participant compensation has been defined with the local partners from Tdh and Cesvi. Participants in the modules 1- 5 will not be compensated individually. However, participants may receive a snack (popcorn) during the observation period (module 2) if this was decided to be needed for observing the occurrence of handwashing before eating. Also, participants attending the focus group discussions and interviews will be offered a snack at the end of the work (water, drink, and sandwich).

9.7 Damage coverage / Insurance

Field staff and collaborators visiting the country are insured by Tdh Lausanne and Cesvi. For the study participants there is no insurance as the project risk class is A.

9.8 Other aspects

Tdh and Cesvi workers are allowed to assist schools with transport, in case an emergency patient needs to be transported to the nearest hospital. Tdh and Cesvi do have official evacuation documents for this instance.

Field workers will be briefed before their deployment to the schools about the sensitive nature of this study setting. They will be informed that they might encounter emergencies. In case that a field worker needs psychological support, Tdh/Cesvi will arrange this.

For the security of the field workers, Tdh and Ccesvi have a security department which is responsible for security protocols and updates concerned staff about the safety of visiting certain areas.

10 FUNDING

This project is funded by the SDC within their research programme called TRANSFORM (2020-2030) (see supplementary files for the contract with SDC). The research team attests that there is no conflict of interest and that this study will be conducted independently of outside influences in terms of specific intellectual, financial, and proprietary agendas.

The budget of the H4H project is available as supplementary document.

11 DISSEMINATION OF RESULTS AND PUBLICATION POLICY

Data can be shared between project partners. Whoever was responsible and or involved in the collection of data, has the right to publish this data. People involved in the data collection will be approached to be a co-author of upcoming publications if they are willing to contribute to the paper writing process.

11.1 Dissemination to scientific community; incl. lead in publications

The results of the research will be presented in scientific publications, project reports, a PhD Thesis at conferences and potentially as a MSc Thesis.

11.2 Information of community and policy makers

Key stakeholders have been involved in the project from the beginning with the kick-off workshop in 2021, followed by the co-production of the theory of change. They will be approached again for interviews in 2023. At the end of the project sanitary and education authorities, policymakers and local key stakeholders will be informed with webinars, sector events and workshops. Former schools which have participated in the study will be informed about the results by the local implementation partners from Tdh and Cesvi.

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