Use of the Smittestopp app for contact tracing: validation study protocol

Version: 1.3

Date: 23 June 2020

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Summary

Given the low number of cases and low number of app users, it is important that we use alternate approaches for validation of Smittestopp so that if the number of cases increases in the future, we can be confident that the algorithms in the app can accurately identify contacts and supplement the manual contact tracing strategies. The objectives of this study are therefore:

- To determine the accuracy of the Smittestopp Bluetooth (BT) and GPS algorithms in reliably identifying contacts and the factors associated with identifying contacts
- To assess the potential for Smittestopp to identify community contacts in different contexts
- To compare the results of the Smittestopp solution with the Google/Apple solution

The results of this study will be used to refine the definition of a close contact for digital tracing, establish modified risk scores and categories within Smittestopp and identify weaknesses and strengths of the Smittestopp solution, including the types of contacts that are not captured by the solution. This information will be used to determine how Smittestopp will be able to complement manual contact tracing, particularly in terms of identifying community contacts. By comparing the results for Smittestopp with the results for the Google/Apple solution, we will be able to choose the best digital tool for contact tracing that is currently available.

Pairs of study participants carrying mobile phones with the test application installed will be asked to follow predefined routes to selected locations for 6-hour periods for four consecutive days. Routes will be designed to ensure that multiple participants will be within close contact at several points throughout the day without interacting directly in order to simulate community contacts. Additional phones with the test app installed will be placed at each of the predefined locations in order to introduce an additional contact point. We will select a variety of locations (such as cafes/restaurants, stores, other indoor public spaces and outdoor public spaces) and routes (by bus, tram and subway and on foot) in order to assess whether close contacts are more easily identified in some contexts than others. This will be repeated over several days in order to assess variability in number of contacts identified by time, type of location, and type of phone. Data collection will take place over four days. For Day 1 and Day 2 of data collection, one set of routes including 20 locations will be used. For Days 3 and 4 of data collection, the second set of routes including 20 new locations will be used. Participants will be organized in five groups of pairs (1, 2, 3, 4 and 5) with common start and end points, but different contact points throughout the day. Groups will be composed to include only Android users, only iOS users and mixed phone type users.

Data will be simultaneously collected in three ways: a) through the test app installed on mobile phones, b) through external GPS tracker, and c) on paper by study participants. We will use the collected data to calculate how many contacts are identified out of the total possible number of contacts that could have been identified, including number of concordant pairs, and identify contexts in which contacts are less likely to be identified (for example by type of location, type of phone and type of contact).

Background and justification

Use of apps for contact tracing

In progress

Since the beginning of the covid-19 outbreak, contact tracing has been a key component of response strategies in many countries (ref). The rapid identification and quarantine of close contacts of confirmed cases has been successful in interrupting transmission chains and reducing spread of the disease (ref). Several countries have pursued digital solutions for contact tracing, using mobile phones to identify contacts based on proximity. Several countries, such as Singapore, Australia, Malaysia and the UK have used Bluetooth-based solutions, while other countries such as Iceland, Ghana, India, Israel and several US states have considered GPS -based solutions. In addition, an Apple/Google solution was recently made available. However, few studies have been published on how well contact tracing apps fulfill their defined objectives and by what measures.

Description of the Norwegian contact tracing app Smittestopp

In Norway, the Smittestopp app was launched on 16 April with two main objectives: 1) to rapidly alert users by SMS if they have been in close contact with another app user who is later confirmed to have covid-19 and 2) to use the anonymized data collected through Smittestopp and stored centrally to see the extent to which people are keeping distance from each other at a population level, particularly as control measures are gradually relaxed (ref). Smittestop uses both GPS positioning and Bluetooth proximity to identify close contact of confirmed covid-19 cases. Data is stored for a maximum of 30 days. The Norwegain Institute of Public Health is permitted to collect information through Smittestopp for these purposes under the *Regulations for digital contact tracing and epidemic control for the covid-19 outbreak*[1]. Smittestopp is free to install, voluntary to use and can be turned on and off by the user. Users are asked to read and agree to the terms of use when downloading the app. Users are free to delete the app and have their personal data deleted at any time. Smittestopp users must be at least 16 years old.

For the purpose of contact tracing, Smittestopp has been linked with the Norwegian Surveillance System for Communicable Diseases (MSIS). As covid-19 is a notifiable condition in Norway, all laboratory-confirmed cases are registered in the MSIS database, which is required under the *Regulations on the notification system for communicable diseases*[2]. Cases are registered in the MSIS database using an 11-digit personal number, which can then be linked to a Smittestopp user's mobile number which is available through the Central Contact and Reservation Register. Only people who have downloaded the app and accepted the terms of use will have case information from MSIS linked to mobile contact information. If a Smittestopp user tests positive for covid-19, other Smittestopp users can be alerted if they were in close contact (within 2 meters for more than 15 minutes) in the three days before the case was tested (reduced from seven days in the initial algorithm).

In Norway, the number of reported covid-19 cases has dropped since the outbreak peaked at over 300 cases daily in mid-March. Since the second week of May there have only been between approximately 10 and 20 cases reported daily. In addition, the number of app users has dropped since the app was launched. Shortly after Smittestopp was launched on 16 April, over 1.5 million people had downloaded the app. However, as of 3 June 2020, there are 592 924 active Smittestopp users.

[1] Regulations for digital contact tracing and epidemic control for the covid-19 outbreak
[2] Regulations on the notification system for communicable diseases

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Previous validation studied for Smittestopp

Several different approaches have already been used to calibrate and validate Smittestopp as a contact tracing tool. These include pre-launch technical validation by the developers, comparison of manual and digital results in three municipalities and testing in controlled test cases using students.

Pre-launch technical validation

Before the launch of Smittestopp, validation of the contact tracing solution was conducted by the developers in several phases from 27 March to 17 April using data from approximately 300 app testers. The main objectives of this phase were to estimate beacon proximity/distance based on the Bluetooth signal strength, evaluate the phone discoverability via Bluetooth and evaluate the tracing algorithms for different types of activities (such as walking, driving, indoor activities and outdoor activities). The results of this validation found that the tracing algorithm was quite accurate in identifying the contact if data is available, but that the contact duration reported in the app differed from ground truth. Additionally, the accuracy of GPS was found to be quite low in indoor locations but seem to provide accurate results for outdoor contacts.

Comparison with manual contact tracing in pilot municipalities

In order to validate the app as a contact tracing tool, from 27 April to 31 May we collaborated with three municipalities to compare the results of manual contact tracing with the contact found through the app. In the 5-week test period, uptake of the app in the test municipalities was X%, (as of 2 June Drammen 14%, Trondheim 14% and Tromsø 12%). Of the 118 cases reported in the three municipalities during the test period, 98 of the cases (83%) were over the age of 15 and could therefore have had access to Smittestopp. In total, 31 of these cases were Smittestopp users. In total, 60 contacts were identified by Smittestopp, of which 24 (40%) were confirmed to be close contacts. Of these, 18 were also found through manual contact tracing (75%). Six contacts were only found through Smittestopp (4%). The main reasons cases were not considered to be true contacts were that the contact was more than 48 hours before onset of symptoms with the case (n=9), the contact had too little contact with a case (n=8), the mobile was used by another person than the name it was registered under (n=2) or the case was asymptomatic (n=1).

The results of the initial validation demonstrated that while Smittestopp was able to identify both contacts already identified through manual contact tracing and additional contacts not already known to contact tracers, the risk score, adapted from the UK, needs to be modified to represent "true" contacts as currently it is a basic version which is not adjusted to the technical contact tracing. The results also reinforce that the added value of a contact tracing app will be to identify contacts not personally known to the case. Given the low numbers of cases and app users, the data collected through the municipalities was too limited to make any conclusions regarding the effectiveness of the app in identifying contacts.

Technical validation of test cases using student participants

A technical validation of the Smittestopp app was conducted between 20 and 22 May 2020 in order to test the performance of the app in 15 different short scenarios. Three groups of three participants (9 participants in total) tested whether the Smittestopp could find other users using both Android and iPhone under different conditions. Although the results of the validation are currently being analysed, it is likely that these tests of short duration will be insufficient to determine the performance of Smittestopp in community settings.

Justification for the current study

Given the low number of cases and low number of app users, it is important that we use alternate approaches for validation of Smittestopp so that if the number of cases increases in the future, we can be confident that the algorithms in the app can accurately identify contacts (risk score is adjusted for digital contact tracing and the Smittestopp technology) and supplement the manual contact tracing strategies. While it is unlikely that digital solutions will be able to fully replace manual contact tracing, Smittestopp may enable the identification of additional contacts, particularly in community settings.

Methods

Objectives

- To determine the accuracy of the Smittestopp Bluetooth (BT) and GPS algorithms in reliably identifying contacts and the factors associated with identifying contacts
- To assess the potential for Smittestopp to identify community contacts in different contexts
- To compare the results of the Smittestopp solution with the Google/Apple solution in identifying contacts in different contexts

The results of this study will be used to refine the definition of a close contact for digital tracing, establish modified risk scores and categories within Smittestopp and identify weaknesses and strengths of the Smittestopp solution, including the types of contacts that are not captured by the solution. This information will be used to determine how Smittestopp will be able to complement manual contact tracing, particularly in terms of identifying community contacts. By comparing the results for Smittestopp with the results for the Google/Apple solution, we will be able to choose the best digital tool for contact tracing that is currently available.

Study population

We will recruit 50 participants for the data collection period (4.5 days, including distribution of data collection tools, training and four days of data collection). The participants will be students recruited via contacts in the project partner institutes. Recruited participants must be familiar with Oslo, including the public transportation system, and should not belong to any of the defined risk groups for covid-19.

Study design

Study participants carrying mobile phones with the test applications installed will be asked to follow predefined routes to selected locations over a 6-hour period. They will be travelling in pairs, to ensure that there will be a known contact in each location throughout the day. Each participant should carry two phones, one with the Smittestopp app and one with the Google/Apple solution, in order to avoid interaction between the two apps on the same phone. Routes will be designed to ensure that multiple participants will be within close contact at several points throughout the day without interacting directly in order to simulate community contact. Additional phones with the test app installed will be placed at each of the predefined locations in order to introduce an additional contact point.

We will select a several locations within a variety of categories (such as cafes/restaurants, stores, other indoor public spaces and outdoor public spaces) and routes (by bus, tram and subway and on foot) in order to assess whether close contacts are more easily identified in some contexts than others. Participants will not follow the same routes to ensure that different combinations of potential contacts are meeting in different locations. This will be repeated over several days in order to assess variability in number of contacts identified by time, type of location, and type of phone.

Operational definitions

Manual contact tracing

In manual contact tracing, close contacts are all people who have been in close contact with a person with confirmed COVID-19 disease from 48 hours before symptom onset and until that person comes out of isolation. A distinction is made between "household members and equivalent close contacts" and "other close contacts". The person responsible for contact tracing decides to which category the person belongs after assessing the infection risk and the type of follow-up required (including recommended test regime and duration of quarantine) differs depending on the type of contact.

Household members or equivalent close contacts are those who live in the same household, those who have had similar close contact as someone in a household (e.g. boyfriend/girlfriend, work colleagues in an open plan office, same cohort in childcare centre or school) and those who have cared for, or had similar close contact, with a person with confirmed COVID-19, without using the recommended protective equipment.

Other close contacts are defined as:

- Any person closer than 2 meters for more than 15 minutes continuously with a person with confirmed COVID-19 disease indoors
- Any person closer than 2 meters for more than 15 minutes continuously, face-to-face, with a person with confirmed COVID-19 disease outdoors
- Any person that has been in direct physical contact with (e.g. shaken hands) with a person with confirmed COVID-19 disease.

Digital contact tracing

Smittestopp

In Smittestopp, BT is primarily used to determine proximity between a case and contacts while GPS allows for identification of location and more accurate identification of the contact duration.

The digital definition of a contact is currently any person in contact with a case with cumulative BT proximity for more than 15 minutes or at least one BT proximity and GPS proximity for at least 30 minutes. Contacts meeting the minimum definition have different risk scores, depending on the proximity and duration of contact. The risk score is calculated as a time integral over 1/distance^2. The risk score is calculated separately for BT and GPS contacts. Once the risk scores for BT and GPS are calculated, the risk category is assigned to each contact as[3]:

- Low: BT risk score is [3.5,7.5] and GPS risk score is [1.25, 2.5]. This corresponds to *BT proximity for at least 15 min at a 2 m distance or at least one BT proximity and GPS proximity for at least 30 minutes at a 4 m distance*
- Medium: BT risk score is [7.5,10] and GPS risk score is [2.5, 4]. This corresponds to *BT proximity for at least 25 min at a 2 m distance or at least one BT proximity and GPS proximity for at least 60 minutes at a 4m distance*
- High: BT risk score is [10,infty] and GPS risk score is [4, infty]. This corresponds to *BT proximity for at least 40 min at a 2 m distance or at least one BT proximity and GPS proximity for at least 60 minutes at a 4 m distance*

If BT and GPS contacts result in different risk categories, the ultimate risk category is chosen as the highest one.

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[3] The categories are provided for a given distance; for different proximities the duration is changed accordingly.

During the validation phase, additional categories have been included to determine minimum values for identified contacts. These include:

- BT under 15 minutes: cumulative BT contact with a total duration < 15 min
- GPS_only: no BT but only GPS contact identified.

These categories will be revised and modified based on the results of the validation phase.

Apple/Google

In progress

Type of location

In GPS, locations or points of interest (PoI) are coded using the following categories:

- Cafes, bars and restaurants
- Universities
- Entertainment and cultural facilities
- Shops/stores
- Sport facilities
- Religious facilities
- Office building/complex or business park
- Public transport stop
- Inside transport (bus, tram, subway, train and ferry)
- Other building (those we were not otherwise able classify)
- Outside

For this study, we have chosen not to include spaces where it is relatively easy to obtain an overview of attendees (childcare centers, schools, offices, nursing homes) and healthcare services (medical offices, hospitals) which often have internal procedures for contact tracing and would require additional consent to include.

Types of modes of transportation

Participants will be asked at various times to travel using the following modes of transportation:

- On foot
- Bus
- Tram
- Subway
- Ferry

Sampling procedure

We will select two sets of up to twenty locations representing different contexts where community transmission of covid-19 may occur. For Day 1 and Day 2 of data collection, one set of up to 20 locations will be used. For Days 3 and 4 of data collection, the second set of up to 20 locations will be used. Participants will be organized in five groups with five pairs each (1, 2, 3, 4 and 5) with common start and end points, but different contact points throughout the day. In Group1, only iOS users will be included, in Group 2 only Android users will be included and in groups 3, 4 and 5 different proportions of Android and iOS users will be included.

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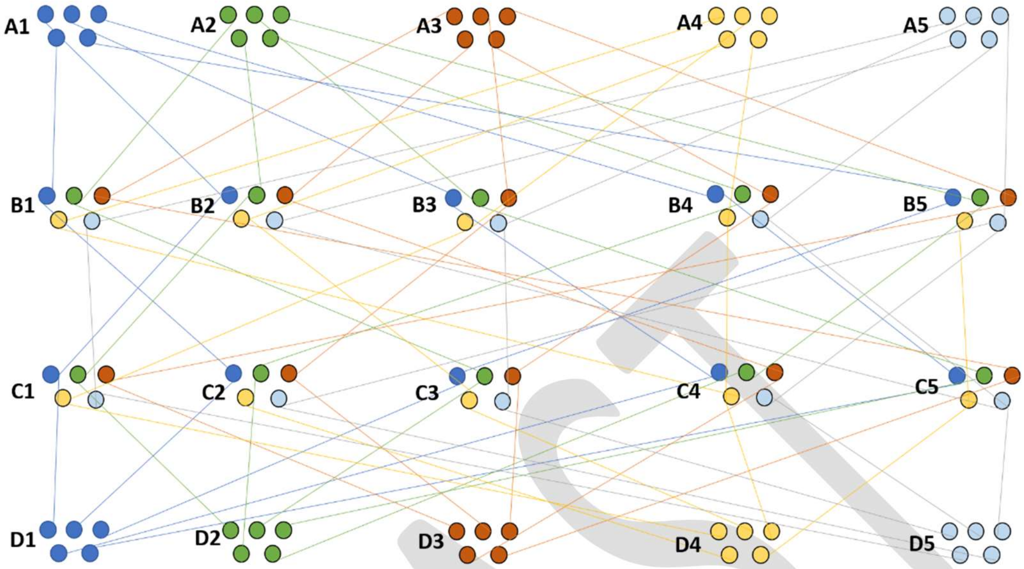
Participants will be asked to be at specific locations in defined windows of time (time slots A, B, C and D) but will not travel in groups to the same locations in order to simulate different travel patterns and have different combinations of participants at the different locations (Figure 1).

Figure 1. Schematic representation of contact points by group (1 to 5) and time slot (A, B, C and D)



Participants will travel the following routes on the different days of data collection:

- Day 1: Participants travel in pre-defined routes from five starting points to pre-define locations (four locations per participant in a day, up to 20 locations in total, different phone types in each group).
- Day 2: Participants travel in the same set of pre-defined routes as Day 1 but will switch so that individual participants are not following the same route as the day before. This will allow us to assess whether a similar number of contacts are identified compared to Day 1 (variability in number of contacts when following the same routes)
- Day 3: Participants travel in pre-defined routes from five new starting points and visiting new locations (four locations per participant in a day, up to 20 locations in total, different phone types in each group). This will allow us to determine if the number of contacts identified is route-dependent (variability in number of contacts when following different routes).
- Day 4: Participants travel in the same set of pre-defined routes as Day 3 but will switch so that individual participants are not following the same route as the day before (variability in number of contacts when following the same routes).

An example of different routes that will be given to participants is provided in Appendix X.

Data collection

For each user we will register the following information:

- A unique number that will be used to identify the participant for all collected data
- The phone type used (Android or iOS) for both phones (Smittestopp and Google/Apple)
- The person (and their unique number) that the participants is paired with for the test period
- The route that the participant is asked to follow on days 1, 2, 3 and 4

Data for each participant will be simultaneously collected in four ways during the four-day test period: a) through the test Smittestopp app installed on a mobile phone, b) through the test Apple/Google app installed on a different mobile phone, c) through an external GPS tracker, and d) on paper by study participants.

Data collection in the test app

The following data will be collected automatically in the test version of the Smittestopp app:

- GPS trajectories
- Time of contact, duration and RSSI value of Bluetooth encounters with other app users

Data collection in Apple/Google app:

- In progress

Data collection through external GPS track

Data from Garmin or other GPS tracker

- Trajectory/location information

Data collection by study participants

Paper-based collection of data (data collection tool in Appendix X)

- Time arriving and departing points of contact
- Mode of travel used
- Estimated number of contacts within 1 meter/ 2 meters at each location and on each mode of transportation
- Specific location in PoI
- Any time not within 1 – 2 meters with paired partner
-

Data analysis

We will calculate how many contacts are identified out of the total possible number of contacts that could have been identified and determine the factors that affect concordance between phones.

Pairs

Each participant will be assigned a partner with whom they will follow the assigned routes. This partner will act as a control as we will know that these pairs will be in close contact at all locations and we expect that these pairs will successfully identify each other as contacts in both apps (concordant matches). Based on the data collected through the apps, GPS, and the paper-based data collected by participants we will determine the following:

- Number of matches and duration of matches via app Bluetooth / GPS between each participant and their partner
- Number of concordant matches and duration of concordant matches for each pair
- Difference in concordant matches by type of location/PoI categories
- Difference in concordant matches by type of phones (iOS to iOS, Android to Android, iOS-Android)

Connections in locations

Number of possible contacts defined as:

- Number of phones at each location during each slot (10 participants plus stationary phone): 11

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- Number of possible of contacts for each phone: 10
- Total number of potential contacts identified at each location: 110
- Total number of potential contacts identified in a study day (110 contacts x 4 locations x 5 slots): 600 x repeated for 4 days = 2400 potential contacts.

Using the information from the app, GPS and paper-based data collection, for each location we will identify:

- The number of potential contacts identified and number of concordant pairs, including if both phones of the pairs connect with both phones of other pairs
- The duration of contact
- The differences in type of phone used
- The accuracy of the location information in the apps

From this information we will identify:

- The locations where most and fewest contacts were found
- The locations with the most and fewest matches with the stationary phone
- The locations with the most and least difference with ground truth
- The connections, concordance, and duration associated with different travel modes and time

Evaluation of Smittestop versus Apple/Google app

- Comparison of indicators between Smittestop and Apple/Google app, specifically
    - Connection of pairs
    - Concordance
    - Type of phone
    - Different locations characteristics

Quality assurance

As part of the protocol development process, we will share the draft plan with experts outside the investigator team as part of a peer review process. This will allow us to identify potential problems at an early stage and make appropriate changes to the planned approach.

For each location, a member of the study team will visit to assess the suitability of the site, collect information that can be included in the participant instructions (e.g. where to sit) and, if necessary, create a diagram, and arrange for placement of the stationary phone.

We will conduct a small pilot study for the study using a group of six participants (three pairs with a combination of Android and iOS phones) and a limited number of locations. The purpose of the pilot will be:

- To ensure the instructions to participants are clear and the data collection tools are appropriate
- To confirm that the estimated times in each location will be sufficient for the expected data collection
- To ensure that the data can be extracted from the provided phones and analysed according to the analysis plan

A half-day training session (Day 0) prior to the start of the data collection (Days 1-4) will be organized to provide participants with routes, ensure the equipment is working correctly and to answer any

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questions. We will provide the phone number of a study coordinator to all participants which they can call during the data collection period if they experience any difficulties.

Bias and limitations

In progress

Protection of human subjects

Risks

Participants will be asked to move around the city in a range of different social situations which may increase exposure to at a time when social distancing is still encouraged, although people are not asked to remain at home unless necessary. We expect that this risk can be mitigated by only inviting people who do not belong to risk groups for covid-19 to participate in the study. During the training prior to data collection, participants will be given advice on how to safely visit each of the sites in line with the existing advice on social distancing and will be provided with hand sanitizer which they can carry during the data collection period.

Benefits

Participants in the study will be provided with a stipend that will cover the costs of the activities that they are asked to do during the study period (e.g. food purchases, admission to venues and public transportation costs). Participants will also be provided with some financial compensation for their time.

The locations/PoI selected will be informed about the purpose of the study and will be asked to participate voluntarily. Participants visiting the locations will be asked to make a purchase or pay for admission.

Confidentiality and informed consent

Participants will be provided with phones that have the test app pre-installed and will not be using their own phones or apps for the purposes of this study. Movement data will not be collected outside the defined data collection times.

Each participant will be provided with a unique identifier which will be used to identify their data from the different sources after data collection is complete. Personal information about the participants will not be collected or used as part of this study.

Participants will be asked to sign a consent form in which they agree to share their movement data during the study period and take responsibility for the data collection tools prior to the start of the study.

Ethical committee clearance

Ethical committee clearance is not required for this study for the following reasons:

- The data being collected will be completely anonymous with no personal information being collected (apart from the name of the participant and a record of consent, which will be separate from the data collected and linked using a unique identifier)
- The data is not considered to be sensitive or confidential in nature. This study does not involve the collection of medical or health-related information and all movement data is being collected under controlled test conditions.
- The issues being researched are not likely to upset or disturb participants

- Vulnerable or dependent groups are not included (anyone under the age of 16 or belonging to a covid-19 risk group will not be included as participants).

Appendices

Data collection instruments

Annex X. Examples of routes for participants by location, time slot and type of transport

Location	Time	Slot 1	Slot 2	Slot 3	Slot 4	Slot 5
	0915	Turn on app/Bluetooth/GPS				
Location A	0930 – 1000	**A1** Kafebrenneriet, Sagene (sit as far to the back as possible)	**A2** Baker Hansen, Majorstua (sit as far to the back as possible)	**A3** Skatten café, Tøyen	**A4** Oslo S	**A5** Aker Brygge
Travel	1000-1030	37 bus from Sagene to Hammersborggata (as far to the back as possible)	On foot from Majorstua to Frognerpark	On foot from Tøyen to Botaniske Hage	30 bus (as far to the back as possible)	Ferry from Aker Brygge to Bygdøy
Location B	1030 – 1130	**B1** Kulturhuset, Sentrum (2nd floor, «biblioteket» if possible)	**B2** Frognerparken (be at monolith from 1100-1105)	**B3** Botaniske Hage (be at the café from 1100 to 1105)	**B4** Deichman bibliotek, Grunerløkka	**B5** Fram Museum, Bygdøy
Travel	1130 - 1200	On foot from Kulturhuset to	20 bus from Frognerparken to	T-bane from Tøyen to Storo (as far to the front as possible)	On foot from to Mathallen, Vulkan	Bus 30 from Bygdøynes to Solli
Location C	1200 - 1300	**C1**	**C2** Skøyen	**C3** Storo storsenter	**C4** Mathallen, Vulkan	**C5** Solliplass
Travel	1300-1330		Flytoget			
Location D	1330-1430	**D1** Oslo Bar & Bowling, Youngstorget	**D2** **Gardermoen**	**D3**	**D4**	**D5**
	1445	Turn off app/Bluetooth/GPS				

Annex X – Data collection sheet for participants

Location	Time	Slot 1	Actual start time	Actual end time	Estimated number of people within 1m of you at this location	Notes (E.g. time apart from partner)
	0915	Turn on app/ Bluetooth/GPS				
Location A	0930 – 1000	**A1** Kafebrenneriet, Sagene (sit as far to the back as possible)				
Travel	1000-1030	37 bus from Sagene to Hammersborggata (as far to the back as possible)				
Location B	1030 – 1130	**B1** Kulturhuset, Sentrum (2nd floor, «biblioteket» if possible)				
Travel		On foot				
Location C	1200 - 1300	**C1**				
Travel	1300-1330					
Location D	1330-1430	**D1 Oslo Bar & Bowling**				
	1445	Turn on app/ Bluetooth/GPS				

Dummy tables

Type of location	Name location day 1 and 2	Name location day 3 and 4
Cafes, bars and restaurants		
Universities		
Entertainment and cultural facilities		
Shops/stores		
Sport facilities		
Religious facilities		
Office building/complex or business park		
Public transport stop		
Inside transport (bus, tram, subway, train and ferry)		

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Other building		
Outside		
Characteristics of the location		
Crowded		
Underground		
One floor / multiple floors		

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