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Cohort profile: Resettlement in Uprooted Groups Explored (REFUGE) – A longitudinal study of mental health and integration in adult refugees from Syria resettled in Norway between 2015 and 2017

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ABSTRACT

Purpose: The REFUGE-study was initiated in order to enhance current knowledge on mental health and quality of life among adult refugees from Syria resettled in Norway. The main aim of the study is to investigate how mental health may affect integration in the years following resettlement. This aim will be pursued by combining data from a longitudinal, three-wave questionnaire survey with data from population-based registries on education; work participation and sick-leave; health-care utilization; and drug prescription. The goal is to incorporate the data in an internationally shared database, the REFUGE-database, where collaborating researchers may access and use data from the study as well as deposit data from similar studies.

Participants: The first wave of the REFUGE-study (REFUGE-I) was launched in November 2018 and completed in September 2019. Of the initial 9,990 sampled individuals, 8,752 were reached either by post or telephone and 902 responded (response rate = 10.3%). The data gathered includes extensive sociodemographic information, pre-, peri- and post-migratory stress variables, and measures of mental health and quality of life. The data also features measures of sleep difficulties, smoking, alcohol and drug use in addition to markers of physical health (e.g. head, neck and back pain).

Findings to date: To date, no findings have been published.

Future plans: The REFUGE-cohort study will conduct a second wave of data collection in 2020. A third wave of data collection is planned in 2021, pending funding. Furthermore, questionnaire data will be linked to population-based registries in Norway after all three waves of data collection have been completed. Registry data will be obtained for time-periods both prior to and after the period of data collection. Finally, pending ethics approval, we will begin the process of merging the Norwegian REFUGE-cohort with existing datasets in Sweden, establishing the extended REFUGE-database.

Strengths and Limitations

- The study features a large sample of both male and female adult refugees from Syria who were resettled in a high-income country between 2015 and 2017.
- Study participants were selected through random sampling from a population-based source population identified using Norway's National Registry – i.e. all refugees from Syria residing in Norway who met inclusion criteria had equal probability of selection.
- The study will use a three-wave survey design which will enable longitudinal tracking of self-reported mental health and other key measures.
- The study will link data from the three-wave, questionnaire survey to data in Norway's large, population-based registries on education, work participation and sick-leave, health-care utilization and drug prescription; as well as to other datasets/data sources within the EU.
- Initial data collection yielded a low response rate, despite extensive recruitment efforts.

INTRODUCTION

The adversities of forced migration make the current population of more than 70 million forcibly displaced people especially vulnerable. Exposure to potentially traumatic events (PTEs) such as torture, war and/or violence-related traumas prior to or during forced migration, as well as post-migration socioeconomic hardships and social isolation constitute profound risks for mental ill health, with potential long-lasting effects[1–3].

Given the aforementioned high burden of mental ill health in refugee populations and the centrality of *functional impairment* in the diagnostic frameworks for PTSD, anxiety and depression in the main diagnostic manuals[4,5], few studies have looked at integration in relation to mental health within refugee populations. The studies available show that general health problems, as well as symptoms of PTSD and depression, are adversely associated with economic and social integration[6,7], with one study finding mental health to be a mediator between post-migration stressors and integration[8]. Longitudinal studies with large sample sizes and rigorous methodology are lacking and therefore warranted in order to better understand the mental health burden of refugees resettled in a host country.

Accordingly, the REFUGE-study was initiated in order to enhance current knowledge on mental health and quality of life among adult refugees from Syria resettled in Norway following the 2011 outbreak of the civil war in Syria. The main objective is to investigate how mental health may affect integration in the years following resettlement. This will be done through a planned longitudinal, three-wave survey design linked to population-based registries in Norway on education; work participation and sick-leave; health-care utilization; and drug prescription.

A broader, secondary aim is to extend the REFUGE-study beyond Norway's borders, through collaboration between the REFUGE-study group in Norway and partner institutions in Sweden and the United Kingdom, forming the REFUGE-consortium. This work, pending ethics approval, will include setting up and servicing a shared database that exploits the research potential that lies within the existing datasets on resettled refugees from Syria in Norway and Sweden ($N > 4{,}500$).

A tertiary, long-term goal is to further expand the REFUGE-database by encouraging researchers in other countries to complete similar, nation-wide data-collections that can be added to the existing database. In turn, given the extensive number of included participants, the REFUGE-database will have ample opportunities to provide unique cross-country,

intersectional, comparative analyses that can provide robust explanatory models of refugees' health and social outcomes, in turn informing social policy and practice.

At the time of writing this cohort profile, the first wave of the three-wave survey design has been completed. The REFUGE-study is registered in the ClincalTrials.gov database (NCT03742128).

COHORT DESCRIPTION

Setting

The study is set in Norway, a high-income country, with a population of 5.3 million people. Approximately 4.5% of the Norwegian population has a refugee background. The Directorate of Immigration (UDI) is the central agency in the Norwegian immigration administration. UDI facilitates lawful immigration and ensures that those who meet the requirements for residency are given an opportunity to come to Norway. Since its onset in 2011, the civil war in Syria has forced more than 6.5 million Syrian citizens to flee the country as refugees, of which an estimated one million have reached Europe, excluding Turkey[9,10]. At the time of primary data collection, forced migrants from Syria therefore constituted the largest group of newly resettled refugees and asylum-seekers in Norway.

Eligibility

The source population for the REFUGE-study cohort was defined by the following three criteria: Potential participants had to be (1) Syrian citizens who arrived in Norway as either a resettlement refugee (quota refugee), an asylum seeker, or through Norway's family reunion program, (2) granted permanent or temporary residency and registered with an address in Norway between January 1, 2015 and December 31, 2017, and finally, (3) 18 years of age or older at the time the sample was drawn from the source population.

These criteria were sent to the Norwegian National Registry (NNR) who generated a list of potential participants (N = 14,350) from their database consisting of all individuals residing in Norway at that time. A simple, random, equal probability sample of 9,990 Syrian citizens was then drawn in August, 2018.

Study preparation and promotion

In initial stages of development, approximately a year before the commencement of the data collection, an early version of the questionnaire was tested in a reception centre. Arabic

speaking asylum seekers filled out the survey and participated in focus groups with the aim of testing and tailoring the questionnaire for length, comprehension and cultural sensitivity. Several amendments to the questionnaire then followed as a result of the feedback obtained in these focus groups. Findings from this preliminary stage also prompted the creation of a user reference-group, consisting of six Syrians living in Norway. This user reference-group served as an advisory board throughout the planning, development and implementation of the study.

Additionally, prior to data collection, a number of strategies were employed in order to inform potential participants about the study and boost participation. Key persons within the community were identified and contacted in order to discuss ways to explain and promote the study through social media and other channels. Based on input from these sources, several short, animated movies were made in Arabic in order to explain why the study was being undertaken, what participation entailed, and how key issues in research, such as informed consent, confidentiality, data handling, and privacy rights, would be handled. REFUGE web and Facebook pages were also created in both Arabic and Norwegian, conveying the same information as the movies, in more detail. The Facebook page, with Q&A, was continuously supervised and moderated by a native Arabic speaker.

In order to reach a wider range of potential participants, in-person and paper-based dissemination of information also took place. Information and Q&A sessions at Adult Education centers (VOs) in Norway's larger cities were held by the REFUGE team members, including an Arabic interpreter from Syria who was involved in the study from the beginning. Information about the study was also sent to local community refugee centers throughout Norway. These centers work with refugees on a daily basis, assisting and counselling them on various matters related to the integration process into Norway.

Sampling

The first wave of the REFUGE-study (REFUGE-I) was launched at the end of November 2018. Each of the 9,990 sampled Syrian refugees were sent an envelope containing the study questionnaire, a cover letter in Arabic and a prepaid return envelope. The cover letter explained the purpose and voluntary nature of the study, what participation entailed, and issues surrounding confidentiality and data handling. It also included a space for willing participants to provide written informed consent in the form of a signature.

The address list provided by the Norwegian National Registry (NNR) included 1,235 addresses where the addressee was either not found or could not be reached. These potential participants were never found and therefore excluded from the study. Current rules for conducting research surveys in Norway prohibit more than one reminder being sent out to non-responders to encourage participation. Based on a small pilot project testing the use of telephone reminders with Arabic speaking personnel conducted on 530 non-responders in the sample, it was decided that telephone reminders would be used for all non-responders with an available telephone number (N = 5,675). Telephone contact was made with less than half of this group (N = 2,087). Table S1 in the supplementary material summarizes the answers given by this group when asked to participate. The telephone reminders were conducted in late March and early April, 2019. A postal reminder which included the questionnaire, the cover letter with informed consent and a prepaid return envelope was also sent out to non-responders who were not reached via telephone (N = 5,000). The postal reminder was sent out in early June, 2019. Figure 1 summarizes the flow of participants through REFUGE-I, and Table 1 provides comparative statistics on participants in REFUGE-I vs. the source and sample population. Of the initial 9,990 sampled individuals, 8,752 were reached either by post or telephone and 902 returned the questionnaire (response rate = 10.3% if non-contacts are excluded). Of the 902 responders, 665 (73.2%) were willing to take part in later waves of the study.

According to the original plan registered at ClinicalTrials.gov, data collection was planned to run for about 6-8 weeks. However, due to a very low response rate at the time of the planned closing date in mid January 2019, the study was extended, and the final closing date was in early September 2019. All procedures concerning the selection and recruitment of participants, including consent procedures, were approved by the Regional Committees for Medical and Health Research Ethics (REC) - Region South East (A) in Norway. Reference number 2017/1252.

Table 1. Demographic characteristics of participants vs. the source and sample populations

	Source population *N* = 14,350		Sample population *N* = 9,990		Participants *N* = 902		Participants willing to take part in subsequent surveys *N* = 665	
	n	(%)	*n*	(%)	*n*	(%)	*n*	(%)
Gender								
Female	5,117	(35.7)	3,552	(35.5)	320	(35.5)	236	(35.5)
Male	9,233	(64.3)	6,446	(64.5)	582	(64.5)	429	(64.5)
Age[1]								
18-29	6,135	(42.8)	4,265	(42.7)	197	(21.8)	148	(22.2)
30-39	4,769	(33.2)	3,315	(33.1)	310	(34.4)	218	(32.8)
40-49	2,263	(15.8)	1,604	(16.0)	230	(25.5)	173	(26.0)
50-64	1,034	(7.2)	721	(7.2)	145	(16.1)	112	(16.9)
>64	149	(1.0)	95	(1.0)	20	(2.2)	14	(2.1)
Civil status[1]								
Unmarried	5,879	(41.0)	4,047	(40.5)	236	(26.1)	176	(26.5)
Married	7,873	(54.8)	5,545	(55.5)	595	(66.0)	433	(65.1)
Other[2]	598	(4.2)	398	(4.0)	71	(7.9)	56	(8.4)
Year granted residency in Norway								
2015	2,993	(20.8)	2,081	(20.8)	N/A[3]		N/A[3]	
2016	7,513	(52.4)	5,267	(52.7)				
2017	3,844	(26.8)	2,652	(26.5)				

[1] Age and civil status for the two participating groups was based on participants' answers in the questionnaire.
[2] Includes widow(er), separated, divorced
[3] Individual-level data on the year residency was granted was not provided by the Norwegian National Registry.

METHODS

Three waves of questionnaire surveys are planned for the REFUGE-study (REFUGE-I, II, and III). Collection for REFUGE-I has already been completed as described above. REFUGE-II and III are scheduled to be carried out roughly one and two years after REFUGE-I, respectively. The questionnaire used will be very similar for all three waves of the study. Key variables are highlighted in Table 2 below.

Table 2. Summary of key measures used in the longitudinal, three-wave, questionnaire survey

	Measure used[1]	Comments
Outcome variables		
Symptoms of PTSD	Harvard Trauma Questionnaire, HTQ	The first 16 items on trauma symptoms in section IV will be used
Symptoms of anxiety and depression	Hopkins Symptom Checklist, HSCL-25	The first 10 of the total 25 items will be used to measure symptoms of anxiety and the last 15 to measure symptoms of depression
Quality of life	World Health Organization Quality of Life assessment, WHOQOL-BREF	The scale consists of 26 items and all will be included
Somatic pain	Questions adapted from the Tromsø Study	10 questions will be used, 5 concerning muscle/joint pain and 5 concerning more general somatic pain
Perceived general health	European Social Survey	2 items from the scale will be included
Sleep difficulties	The Bergen Insomnia Scale	The scale consists of 6 items and all will be included
Predictor variables		
Potentially traumatic experiences *before* the flight from Syria (pre-migratory PTEs)	The Refugee Trauma History Checklist, RTHC	The scale consists of 8 items and all will be included
Potentially traumatic experiences *during* the flight from Syria (peri-migratory PTEs)	The Refugee Trauma History Checklist, RTHC	The scale consists of 8 items and all will be included
Post-migration stressful experiences	Post-migration stress scale	The scale consists of 24 items and all will be included
Social support	ENRICHD Social Support Inventory	The first 6 items of the scale will be included

[1] Further information on the measures used can be found in the ClinicalTrial.gov database where the study is registered (NCT03742128)

Measures

In addition to the outcome variables listed in Table 2, the following measures are included in the questionnaire:

Outcomes

Complementary to the Harvard Trauma Questionnaire, an item is included regarding re-experiencing traumatic events or intrusive memories, which asks whether the participant experiences this, how often, and how distressing this is. Also included in the questionnaire is an item on daily effects of chronic physical illness, disability, infirmity or mental health problem/s.

Predictors

In addition to the predictors listed in Table 2, the survey includes questions regarding violence and threats experienced since the participant's arrival in Norway, such as physical violence, threats, and theft. As an addition to the social support scale (ESSI), 3 items have been included to assess how easily the respondent can get help from neighbours, how many people the participant can count on when serious problems occur, and how much concern people show in what the respondent is doing.

Sociodemographics

Important background and demographic variables include: gender, age, marital status, number of children, education, refugee status upon arrival (i.e. asylum seeker, quota refugee, family reunion, or other), whether the participant fled Syria alone or with a partner, family and/or friends, whether other family members had already settled in Norway prior to refugee's arrival in the country, time elapsed between when a participant fled Syria and arrived in Norway, and time in Norway prior to participating in the study. Tables 3 and 4 provide descriptive statistics on participants on the aforementioned variables from the first wave of data collection. The number of participants with missing values across variables can be interpreted from the table (applies for all tables).

Additional sociodemographic data collected include: smoking; alcohol and drug use; employment status; job satisfaction; self-reported competence in English and Norwegian language; and years of education completed. Further details on the scales used, their psychometric properties and how variables will be handled in analyses can be found in the ClinicalTrials.gov registration (NCT03742128).

The administration and logistics of the survey was handled by the research and consulting firm, Ipsos, which has extensive experience with and infrastructure for these types of surveys.

Ipsos is also responsible for securely storing participants' Norwegian identity numbers so that longitudinal tracking of individuals and linking to registry data is possible. The identity numbers are unknown to all researchers involved.

Table 3. Descriptive statistics on participating refugees from Syria

	Participants, *N* = 902		Participants willing to take part in longitudinal questionnaire survey, *N* = 665	
	n	(%)	*n*	(%)
Number of children				
I do not have children	271	(31.6)	213	(33.5)
1	63	(7.4)	44	(6.9)
2	125	(14.6)	86	(13.5)
3	139	(16.2)	103	(16.2)
4	101	(11.8)	78	(12.3)
5	77	(9.0)	53	(8.3)
6 or more	81	(9.5)	59	(9.3)
Total	857	(100.0)	636	(100.0)
Education				
9 years or less	394	(44.7)	281	(43.0)
10-12 years	158	(17.9)	116	(17.8)
More than 12 years	330	(37.4)	256	(39.2)
Total	882	(100.0)	653	(100.0)
Refugee status upon arrival				
Asylum seeker	454	(52.5)	325	(51.0)
Quota refugee	273	(31.6)	209	(32.8)
Family reunion	133	(15.4)	100	(15.7)
Other	4	(0.5)	3	(0.5)
Total	864	(100.0)	637	(100.0)
Arrived in Norway...				
…alone	247	(28.1)	182	(28.0)
…with friends, but no family	56	(6.4)	43	(6.6)
…with family	576	(65.5)	425	(65.4)
Total	879	(100.0)	650	(100.0)
Family member previously settled in Norway				
No	594	(68.3)	440	(68.4)
Yes	276	(31.7)	203	(31.6)
Total	870	(100.0)	643	(100.0)
Length of flight[1]				
Less than 3 months	165	(33.7)	124	(33.9)
3 to 12 months	61	(12.4)	42	(11.5)
1 to 2 years	59	(12.0)	43	(11.7)
2 to 3 years	77	(15.7)	56	(15.3)
More than 3 years	128	(26.1)	101	(27.6)
Total	490	(100.0)	366	(100.0)
Residency time in Norway[2]				
Less than 2 years	104	(16.8)	83	(17.9)
Between 2 and 3 years	151	(24.4)	120	(25.9)
Between 3 and 4 years	289	(46.7)	209	(45.1)
More than 4 years	75	(12.1)	51	(11.0)
Total	619	(100.0)	463	(100.0)

[1] Estimated through the number of days elapsed between a refugee reportedly left Syria and arrived in Norway
[2] Estimated through the number of days elapsed between a refugee reportedly arrived in Norway and the date he/she returned the questionnaire

Table 4. Potentially traumatic experiences prior to and during the flight from Syria among participants

		Participants *N* = 902[1]		Participants willing to take part in longitudinal survey *N* = 665[1]	
		n	(%)	*n*	(%)
***Before* you left your home, have you personally faced any of the following situations or events:**					
War at close quarters	No	41	(4.7)	31	(4.8)
	Yes	840	(95.3)	618	(95.2)
Forced separation from family or close friends	No	324	(40.3)	235	(39.8)
	Yes	480	(59.7)	355	(60.2)
Loss or disappearance of family member(s) or loved one(s)	No	287	(35.3)	213	(35.5)
	Yes	526	(64.7)	387	(64.5)
Physical violence or assault	No	554	(70.5)	400	(69.3)
	Yes	232	(29.5)	177	(30.7)
Witnessing physical violence or assault	No	304	(36.9)	203	(33.5)
	Yes	520	(63.1)	403	(66.5)
Torture	No	567	(72.8)	410	(71.6)
	Yes	212	(27.2)	163	(28.4)
Sexual violence	No	710	(93.3)	518	(92.7)
	Yes	51	(6.7)	41	(7.3)
Other frightening situation(s) where you felt your life was in danger	No	103	(12.0)	74	(11.7)
	Yes	754	(88.0)	561	(88.3)
***After* you left your home, during your flight, have you personally faced any of the following situations or events:**					
War at close quarters	No	408	(49.3)	310	(50.7)
	Yes	420	(50.7)	302	(49.3)
Forced separation from family or close friends	No	412	(52.5)	298	(51.5)
	Yes	373	(47.5)	281	(48.5)
Loss or disappearance of family member(s) or loved one(s)	No	422	(53.8)	312	(53.6)
	Yes	362	(46.2)	270	(46.4)
Physical violence or assault	No	638	(83.6)	467	(83.5)
	Yes	125	(16.4)	92	(16.5)
Witnessing physical violence or assault	No	566	(72.6)	405	(70.7)
	Yes	214	(27.4)	168	(29.3)
Torture	No	657	(86.8)	481	(87.1)
	Yes	100	(13.2)	71	(12.9)
Sexual violence	No	722	(97.3)	529	(97.2)
	Yes	20	(2.7)	15	(2.8)
Other frightening situation(s) where you felt your life was in danger	No	350	(42.8)	258	(42.9)
	Yes	468	(57.2)	344	(57.1)

[1] Not all participants answered all items, therefore, the total number of answers for a given item may be less than 902 and 665 for the two groups, respectively.

Registry data

As part of the consent procedure, the cover letter explained that participation in the study entailed that questionnaire data would be linked to registry data in the following Norwegian registries: National education database, NUDB (provides education statistics on an individual level from 1970 up until the present); employment and sick-leave databases (contain individual level data on work-participation and doctor-certified sickness absence from work); Norwegian Prescription Database, NorPD (contains individual level data on all prescription drugs dispensed by pharmacies in Norway); the KUHR database (contains individual level data on the utilization of primary health care services in Norway - e.g. primary care doctors and physiotherapists); and the Norwegian Patient Registry, NPR (contains individual level data on the utilization of specialized health care in Norway).

Patient and public involvement

The REFUGE-study was supported throughout the development process by members of the community. Focus groups were held in the early stages of development in order to tailor the questionnaire, and a user reference group was created in order to act as an advisory group, providing insight during the planning, development and implementation stages. Community members were also involved in the recruitment process, providing insight and advice on the dissemination of information about the study through social media.

Findings to date

The first wave of data collection in Norway has been completed. At the time of writing, no findings have been published.

Strengths and limitations

The REFUGE-study has several important strengths, both in terms of methodology, and in value of the resulting data. Firstly, the study population was randomly selected from a large source population consisting of all adult refugees from Syria residing in Norway who met the study's eligibility criteria, obtained from the Norwegian National Registry. In comparison, many of the previous studies on mental health in refugee populations rely on convenience sampling. Further, the use of a three-wave longitudinal survey design will allow for better exploration of cause-effect relationships between variables in the study, than purely cross-sectional data. In addition, research on the association between refugee mental health and

integration is scarce. By linking longitudinal questionnaire data to registry data on education-, work- and health-related parameters, the study could make important contributions to the dearth of evidence on this topic. Also, combining self-report data with registry data from well-established national registries may reduce common method bias. Research on refugee mental health to date relies heavily on self-report data. A further strength of the study is that most of the key variables are measured using well-documented and validated scales. Review articles on refugee mental health frequently highlight the large degree of variance in terms of methods used, and call for increased focus on methodological issues. Lastly, the close collaboration between the REFUGE-study group in Norway and its main collaborating partner, the Red Cross University College in Sweden, will offer ample opportunities to compare Syrian refugee populations in two different countries, as both projects use similar measures and have agreed to collaborate on and combine datasets.

An important potential weakness of REFUGE-I is that less than 11 percent of the sampled population participated in the study. This could lead to selection bias problems. As can be seen from Table 1, participants are very similar to the source and sample population in terms of gender, though the proportion of young and unmarried refugees are notably smaller in the participating group. Table S2 in the supplementary material shows that the geographical distribution across Norway's 18 counties was very similar for participants and the sample population. In terms of residency status, participants had the same proportional breakdown as the sample population: 95% had temporary residency in Norway at the time of the survey and 5% had permanent residency (result not shown in tables). In order to further explore selection bias, we investigated whether there were any trends across demographic and background variables in terms of when the surveys were filled out and returned. Given that the survey was open for nine months, exploring the timing of participation may give some indication of different groups' willingness to participate, and, by extension, suggest which groups may be over- and underrepresented among participants.

Table S3 in the supplementary material shows the distribution of demographic variables across 4 different time-periods of participation (i.e. the 9-month period the survey was open was divided into 4 shorter periods), and Table S4 shows the distribution across background characteristics related to refugee status and history. Differences in distributions across time-periods were tested with chi-square test of equal proportion. As can be seen from the tables, there was weak or no evidence that the timing of participation was related to

demographic and/or background variables with three exceptions. First, there was very clear evidence that residency time in Norway was negatively associated with early participation - i.e. the longer a refugee's residency time in Norway, the less likely (s)he was to participate in the first time-periods following study launch ($p < 0.001$), relatively speaking. There was also very strong statistical evidence ($p < 0.001$) that pre-migratory stress was associated with the timing of participation, though the underlying trend was not easily interpretable. Refugees with the highest number of potentially traumatic pre-flight experiences (PTEs) were more likely to participate in the early periods after study launch (relatively speaking). This was not true, however, for the refugee group with the second to most PTEs. Lastly, there was moderate evidence that refugee status upon arrival was association with the timing of participation ($p = 0.01$), though no clear underlying pattern was evident.

Another limitation of the present study is the survey design used to attain prevalences of depression, anxiety and PTSD symptoms. Short-form questionnaires, while efficient, do not capture all aspects of the measured constructs. Additionally, recent studies have suggested that when self-report measures are used, resulting prevalences tend to be higher than when using diagnostic interviews[14,15]. However, the questionnaires used in the current study to measure PTSD, anxiety and depression have been validated for use within the studied population and their use allows for many more participants to be reached, improving the generalizability of the findings.

Perhaps the most significant learning opportunity provided by the present study thus far has been the challenging recruitment process. Although extensive recruitment efforts were employed, the participation rate for REFUGE-I was just above 10%. As noted previously, methods to boost recruitment involved the utilisation of contacts within the community, dedicated Facebook and web pages in Arabic, and Q&A sessions held at Adult Education centres in Norway's major cities, as well as the dissemination of information about the project online through purpose-built, animated videos and newsletters. Researchers aiming to gather data from similar populations would do well to ensure that sufficient time and resources are dedicated to the recruitment phase of the study.

Future plans

The REFUGE-cohort study will conduct a second wave of data collection in 2020. A third wave of data collection is planned in 2021, pending funding. Furthermore, we plan to link questionnaire data to Norwegian registry data after all three waves of data collection have

been completed. Registry data will be obtained for time-periods both prior to and after the three-wave survey. Primary and secondary objectives with detailed plans for analyses for studies involving registry data will be registered at ClinicalTrials.gov prior to obtaining the registry data, so that true hypothesis-testing studies from the REFUGE-cohort are distinguishable from more exploratory and data-driven studies. Finally, pending ethics approval, we will begin the process of merging the Norwegian REFUGE-cohort with existing datasets in Sweden, creating the REFUGE-database.

Parallel to completing the survey data collection, data-merging and registry data obtainment, we aim to publish papers in accordance with our pre-registered publication plan at ClinicalTrials.gov.

COLLABORATION

We welcome potential collaboration with other research groups. Interested researchers should contact the REFUGE research group for collaboration and knowledge-sharing. Locally collected data can then be added to the REFUGE-database. Reference estimates (e.g. prevalence, incidence and associations) can then be continuously updated and made available to researchers abiding by the EU's GDPR laws and regulations. In addition, the REFUGE-database will also include data obtained through Scandinavian social and health-registries.

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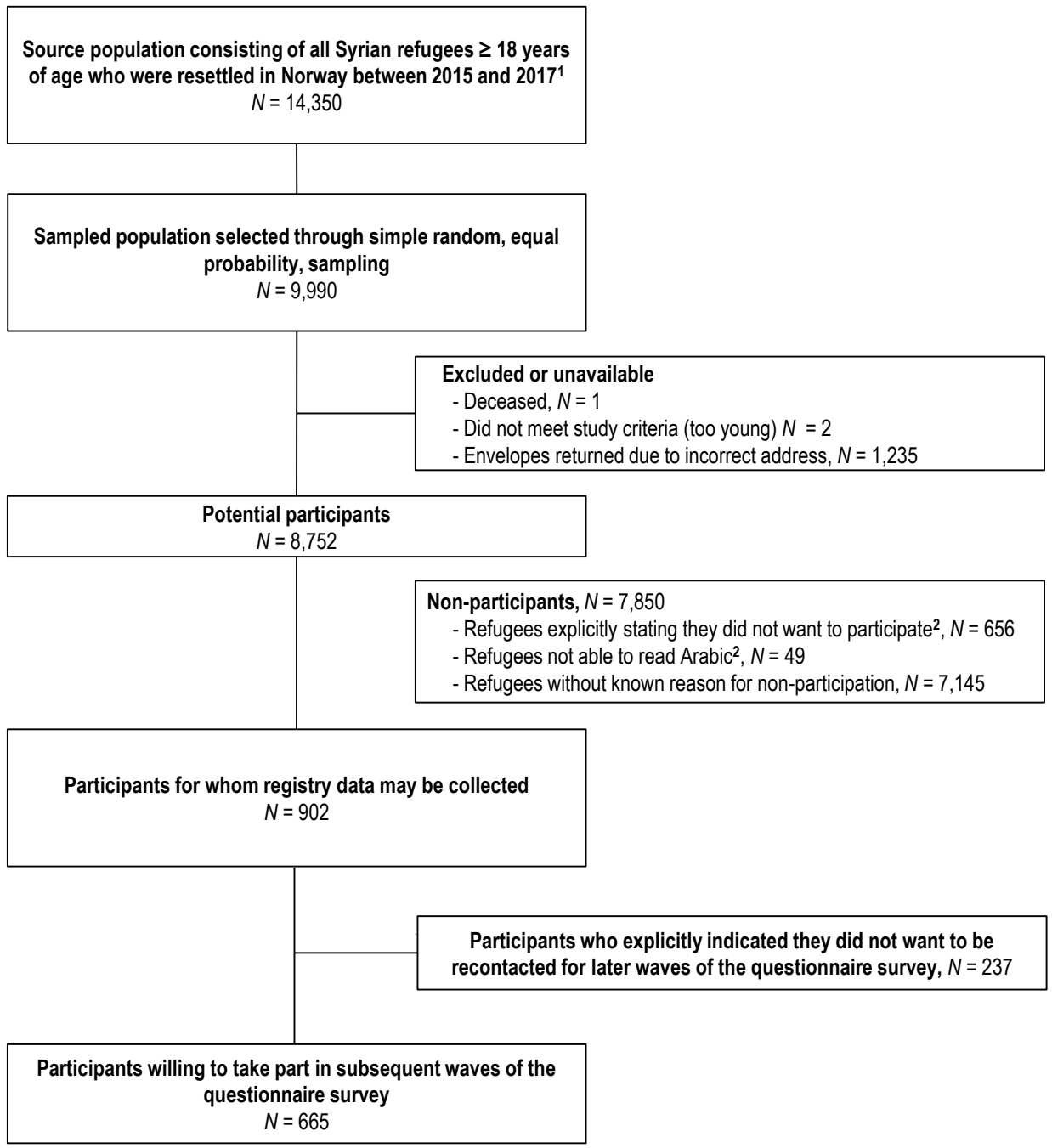

[1] Refugees were either resettlement/quota refugees; asylum seekers who were granted asylum in Norway; or individuals coming through the program *Family immigration with a person who has protection (asylum) in Norway*. The source population was identified through the Norwegian National Registry (NNR)

[2] Information was obtained when non-responders were contacted during the telephone reminder

Table S1. Responses given by initial non-responders during telephone reminder sessions (*N* = 2,087)

	N	**(%)**
Answers given by refugees		
Would like to participate and does not need a new questionnaire	403	(19.1)
Would like to participate and needs a new questionnaire	856	(40.8)
Does not want to participate	656	(30.8)
Moved and wants a new questionnaire	69	(3.3)
Moved and does not want a new questionnaire	29	(1.4)
Wrong number/person	25	(1.2)
Does not understand Arabic	49	(2.4)
Total	**2,087**	**(100.0)**

Table S2. Geographical distribution across Norway's 18 counties for participants and sample population of refugees from Syria

	Sample population *N* = 9,990		Participants *N* = 902	
	n	(%)	*n*	(%)
Akershus	703	(7.0)	52	(5.7)
Aust-Agder	347	(3.5)	30	(3.3)
Buskerud	470	(4.7)	39	(4.3)
Finnmark	254	(2.5)	23	(2.6)
Hedmark	311	(3.1)	30	(3.3)
Hordaland	1,009	(10.1)	88	(9.8)
Møre og Romsdal	486	(4.9)	51	(5.7)
Nordland	670	(6.7)	65	(7.2)
Oppland	381	(3.8)	37	(4.1)
Oslo	773	(7.7)	70	(7.9)
Rogaland	831	(8.3)	63	(7.0)
Sogn og Fjordane	380	(3.8)	34	(3.8)
Telemark	398	(4.0)	40	(4.4)
Troms	449	(4.5)	51	(5.7)
Trøndelag	1,049	(10.5)	96	(10.5)
Vest-Agder	520	(5.2)	50	(5.5)
Vestfold	475	(4.8)	44	(4.9)
Østfold	484	(4.9)	39	(4.3)
Total	9,990	(100.0)	902	(100.0)

Table S3. Demographic characteristics of participating refugees from Syria according to *when* they returned the questionnaire

	4th quarter 2018		1st quarter 2019		2nd quarter 2019		3rd quarter 2019		Total		Chi-square
	n	(%)	*n*	(%)	*n*	(%)	*n*	(%)	*n*	(%)	
Gender											0.08
Male	278	(64.2)	66	(69.5)	157	(68.0)	77	(55.8)	578	(64.4)	
Female	155	(35.8)	29	(30.5)	74	(32.0)	61	(44.2)	319	(35.6)	
Total	433	(100.0)	95	(100.0)	231	(100.0)	138	(100.0)	897	(100.0)	
Age groups											0.36
18-29	87	(20.1)	28	(29.5)	50	(21.6)	31	(22.5)	196	(21.9)	
30-39	142	(32.8)	28	(29.5)	88	(38.1)	50	(36.2)	308	(34.3)	
40-49	122	(28.2)	19	(20.0)	52	(22.5)	36	(26.1)	229	(25.5)	
50-64	72	(16.6)	19	(20.0)	37	(16.1)	16	(11.6)	140	(15.6)	
>64	10	(2.3)	1	(1.0)	4	(1.7)	5	(3.6)	24	(2.7)	
Total	433	(100.0)	95	(100.0)	231	(100.0)	138	(100.0)	897	(100.0)	
Civil status											0.10
Unmarried	121	(27.9)	31	(32.6)	60	(26.0)	22	(15.9)	234	(26.1)	
Married	276	(63.7)	58	(61.1)	154	(66.7)	104	(75.4)	592	(66.0)	
Other[1]	36	(8.3)	6	(6.3)	17	(7.4)	12	(8.7)	71	(7.9)	
Total	433	(100.0)	95	(100.0)	231	(100.0)	138	(100.0)	897	(100.0)	
Education											0.53
9 years or less	187	(44.4)	38	(42.2)	111	(48.7)	53	(38.4)	389	(44.4)	
10-12 years	74	(17.6)	18	(20.0)	35	(15.4)	31	(22.5)	158	(18.0)	
More than 12 years	160	(38.0)	34	(37.8)	82	(36.0)	54	(39.1)	330	(37.6)	
Total	421	(100.0)	90	(100.0)	228	(100.0)	138	(100.0)	877	(100.0)	

[1] Includes: divorced, widow(er), separated

Table S4. Refugee and migratory characteristics of participating refugees from Syria according to *when* they returned the questionnaire

	4th quarter 2018		1st quarter 2019		2nd quarter 2019		3rd quarter 2019		Total		Chi-square
	n	(%)	*n*	(%)	*n*	(%)	*n*	(%)	*n*	(%)	
Ref. status upon arrival											0.01
Asylum seeker	208	(50.5)	54	(61.4)	122	(54.7)	66	(48.5)	450	(52.4)	
Quota refugee	147	(35.7)	20	(22.7)	70	(31.4)	35	(25.7)	272	(31.7)	
Family reunion	55	(13.3)	14	(15.9)	31	(13.9)	33	(24.3)	133	(15.5)	
Other	2	(0.5)	0	(0.0)	0	(0.0)	2	(1.5)	4	(0.5)	
Total	412	(100.0)	88	(100.0)	223	(100.0)	136	(100.0)	859	(100.0)	
Arrived in Norway...											0.47
…alone	121	(28.8)	30	(32.6)	64	(28.1)	31	(23.0)	246	(28.1)	
…with friends only	31	(7.4)	7	(7.6)	11	(4.8)	7	(5.2)	56	(6.4)	
…with family	268	(63.8)	55	(59.8)	153	(67.1)	97	(71.9)	573	(65.5)	
Total	420	(100.0)	92	(100.0)	228	(100.0)	135	(100.0)	875	(100.0)	
Length of flight											0.58
Less than 3 months	73	(31.2)	20	(39.2)	42	(33.6)	30	(37.5)	165	(33.7)	
3 to 12 months	24	(10.3)	6	(11.8)	17	(13.6)	14	(17.5)	61	(12.4)	
1 to 2 years	31	(13.2)	7	(13.7)	15	(12.0)	6	(7.5)	59	(12.0)	
2 to 3 years	34	(14.5)	7	(13.7)	22	(17.6)	14	(17.5)	77	(15.7)	
More than 3 years	72	(30.8)	11	(21.6)	29	(23.2)	16	(20.0)	128	(26.1)	
Total	234	(100.0)	51	(100.0)	125	(100.0)	80	(100.0)	490	(100.0)	
Residency time in Norway											<0.001
Less than 2 years	69	(22.9)	12	(18.5)	16	(10.3)	7	(7.2)	104	(16.8)	
2-3 years	73	(24.3)	14	(21.5)	38	(24.4)	26	(26.8)	151	(24.4)	
3-4 years	140	(46.5)	32	(49.2)	76	(48.7)	41	(42.3)	289	(46.7)	
More than 4 years	19	(6.3)	7	(10.8)	26	(16.7)	23	(23.7)	75	(12.1)	
Total	301	(100.0)	65	(100.0)	156	(100.0)	97	(100.0)	619	(100.0)	
PTEs before flight[1]											<0.001
0-1	34	(7.9)	10	(10.6)	34	(14.8)	15	(11.3)	93	(10.5)	
2-3	101	(23.4)	25	(26.6)	86	(37.4)	29	(21.8)	241	(27.1)	
4-5	185	(42.9)	34	(36.2)	75	(32.6)	64	(48.1)	358	(40.3)	
>5	111	(25.8)	25	(26.6)	35	(15.2)	25	(18.8)	196	(22.1)	
Total	431	(100.0)	94	(100.0)	230	(100.0)	133	(100.0)	888	(100.0)	
PTEs during flight[1]											0.46
0-1	154	(36.8)	31	(34.1)	96	(42.7)	54	(41.9)	335	(38.8)	
2-3	143	(34.2)	32	(35.1)	71	(31.6)	33	(25.6)	279	(32.3)	
4-5	89	(21.3)	19	(20.9)	48	(21.3)	32	(24.8)	188	(21.8)	
>5	32	(7.7)	9	(9.9)	10	(4.4)	10	(7.7)	61	(7.1)	
Total	418	(100.0)	91	(100.0)	225	(100.0)	129	(100.0)	863	(100.0)	

[1] All individuals with at least one answered item on the PTE-scale were given a sum-score for total PTEs before/during flight

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Cohort profile: Resettlement in Uprooted Groups Explored (REFUGE) – A longitudinal study of mental health and integration in adult refugees from Syria resettled in Norway between 2015 and 2017

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Cohort profile: Resettlement in Uprooted Groups Explored (REFUGE) – A longitudinal study of mental health and integration in adult refugees from Syria resettled in Norway between 2015 and 2017

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ABSTRACT

Purpose: In the field of forced migration and mental health research, longitudinal studies with large sample sizes and rigorous methodology are lacking. Therefore, the REFUGE-study was initiated in order to enhance current knowledge on mental health and quality of life among adult refugees from Syria resettled in Norway. The main aim of the study is to investigate how mental health may affect integration in the years following resettlement. This aim will be pursued by combining data from a longitudinal, three-wave questionnaire survey with data from population-based registries on education; work participation and sick-leave; health-care utilization; and drug prescription. The goal is to incorporate the data in an internationally shared database, the REFUGE-database, where collaborating researchers may access and use data from the study as well as deposit data from similar studies.

Participants: The first wave of the REFUGE-study (REFUGE-I) was launched in November 2018 and completed in September 2019. Of the initial 9,990 sampled individuals, 8,752 were reached either by post or telephone and 902 responded (response rate = 10.3%). The data gathered includes extensive sociodemographic information, pre-, peri- and post-migratory stress variables, and measures of mental health and quality of life. The data also features measures of sleep difficulties, smoking, alcohol and drug use, and self-reported physical health (e.g. head and neck pain).

Findings to date: To date, no findings have been published.

Future plans: The REFUGE-cohort study will conduct two additional data collections (2020 and 2021). Furthermore, questionnaire data will be linked to population-based registries after all three waves of data collection have been completed. Registry data will be obtained for time-periods both prior to and after the period of data collection. Finally, pending ethics approval, we will begin the process of merging the Norwegian REFUGE-cohort with existing datasets in Sweden, establishing the extended REFUGE-database.

Strengths and Limitations

- The study features a large sample of both male and female adult refugees from Syria who were resettled in a high-income country between 2015 and 2017.
- Study participants were selected through random sampling from a population-based source population identified using Norway's National Registry – i.e. all refugees from Syria residing in Norway who met inclusion criteria had equal probability of selection.
- The study will use a three-wave survey design which will enable longitudinal tracking of self-reported mental health and other key measures
- The study will link data from the three-wave, questionnaire survey to data in Norway's large, population-based registries on education, work participation and sick-leave, health-care utilization and drug prescription; as well as to other datasets/data sources within the EU.
- Initial data collection yielded a low response rate, despite extensive recruitment efforts.

INTRODUCTION

The adversities of forced migration make the current population of more than 70 million forcibly displaced people especially vulnerable[1]. Here, the concept of "vulnerability" refers to refugees' heightened exposure to potentially traumatic events (PTEs) such as torture, war and/or violence-related traumas prior to or during forced migration, as well as experiences of post-migration socioeconomic hardships and social isolation. Together, these risk factors create a vulnerability that constitutes a profound risk for mental ill health and reduced quality of life with potential long-lasting effects[2–4].

Given the aforementioned high burden of mental ill health in refugee populations and the centrality of *functional impairment* in the diagnostic frameworks for PTSD, anxiety and depression in the main diagnostic manuals[5,6], few studies have looked at integration in relation to mental health within refugee populations. The studies available show that general health problems, as well as symptoms of PTSD and depression, are adversely associated with economic and social integration[7,8], with one study finding mental health to be a mediator between post-migration stressors and integration[9]. Still, longitudinal studies with large sample sizes and rigorous methodology are lacking and the socio-political controversy that is linked to the topic of refugee health often influences the measures and investigative methods used[10]. Therefore, studies that bridge these gaps are warranted in order to better understand the resettlement stressors and the mental health burden of refugees resettled in a host country in order to inform policy and practice.

Accordingly, the REFUGE-study was initiated in order to enhance current knowledge on mental health and quality of life among adult refugees from Syria resettled in Norway following the 2011 outbreak of the civil war in Syria. The main objective is to investigate how mental health may affect integration in the years following resettlement. This will be done through a planned longitudinal, three-wave survey design linked to population-based registries in Norway on education; work participation and sick-leave; health-care utilization; and drug prescription.

A broader, secondary aim is to extend the REFUGE-study beyond Norway's borders, through collaboration between the REFUGE-study group in Norway and partner institutions in Sweden and the United Kingdom, forming the REFUGE-consortium. This work, pending ethics approval, will include setting up and servicing a shared database in order to harness the

research potential that lies within the existing datasets on resettled refugees from Syria in Norway and Sweden (N > 4,500).

A tertiary, long-term goal is to further expand the REFUGE-database by encouraging researchers in other countries to complete similar, nation-wide data-collections that can be added to the existing database. In turn, given the extensive number of included participants, the REFUGE-database will have ample opportunities to provide unique cross-country, intersectional, comparative analyses that can provide robust explanatory models of refugees' health and social outcomes, in turn informing social policy and practice.

At the time of writing this cohort profile, the first wave of the three-wave survey design has been completed. The REFUGE-study is registered in the ClincalTrials.gov database (NCT03742128).

COHORT DESCRIPTION

Setting

The study is set in Norway, a high-income country, with a population of 5.3 million people[11]. Approximately 4.5% of the Norwegian population has a refugee background[12].The Directorate of Immigration (UDI) is the central agency in the Norwegian immigration administration. UDI facilitates lawful immigration and administrates applications for residency and citizenship, including asylum applications[for details, please see 13]. Since its onset in 2011, the civil war in Syria has forced more than 6.5 million Syrian citizens to flee the country as refugees, of which an estimated one million have reached Europe, excluding Turkey[14,15]. At the time of primary data collection, forced migrants from Syria therefore constituted the largest group of newly resettled refugees and asylum-seekers in Norway.

Eligibility

The source population for the REFUGE-study cohort was defined by the following three criteria: Potential participants had to be (1) Syrian citizens who arrived in Norway as either a resettlement refugee (quota refugee), an asylum seeker, or through Norway's family reunion program, (2) granted permanent or temporary residency and registered with an address in Norway between January 1, 2015 and December 31, 2017, and finally, (3) 18 years of age or older at the time the sample was drawn from the source population.

These criteria were sent to the Norwegian National Registry (NNR) who generated a list of potential participants (N = 14,350) from their database consisting of all individuals residing in Norway at that time. A simple, random, equal probability sample of 9,990 Syrian citizens was then drawn in August, 2018.

Study preparation and promotion

In initial stages of development, approximately a year before the commencement of the data collection, an early version of the questionnaire was tested in a reception centre. Arabic speaking asylum seekers filled out the survey and participated in focus groups with the aim of testing and tailoring the questionnaire for length, comprehension and cultural sensitivity. Several amendments to the questionnaire then followed as a result of the feedback obtained in these focus groups. Findings from this preliminary stage also prompted the creation of a user reference-group, consisting of six Syrians living in Norway. This user reference-group served as an advisory board throughout the planning, development and implementation of the study.

Additionally, prior to data collection, a number of strategies were employed in order to inform potential participants about the study and boost participation. Key persons within the community were identified and contacted in order to discuss ways to explain and promote the study through social media and other channels. Based on input from these sources, several short, animated movies were made in Arabic in order to explain why the study was being undertaken, what participation entailed, and how key issues in research, such as informed consent, confidentiality, data handling, and privacy rights, would be handled. REFUGE web and Facebook pages were also created in both Arabic and Norwegian, conveying the same information as the movies, in more detail. The Facebook page, with Q&A, was continuously supervised and moderated by a native Arabic speaker.

In order to reach a wider range of potential participants, in-person and paper-based dissemination of information also took place. Information and Q&A sessions at Adult Education centers (VOs) in Norway's larger cities were held by the REFUGE team members, including an Arabic interpreter from Syria who was involved in the study from the beginning. Information about the study was also sent to local community refugee centers throughout Norway. These centers work with refugees on a daily basis, assisting and counselling them on various matters related to the integration process into Norway.

Sampling

The first wave of the REFUGE-study (REFUGE-I) was launched at the end of November 2018. Each of the 9,990 sampled Syrian refugees were sent an envelope containing the study questionnaire, a cover letter in Arabic and a prepaid return envelope. The cover letter explained the purpose and voluntary nature of the study, what participation entailed, and issues surrounding confidentiality and data handling. It also included a space for willing participants to provide written informed consent in the form of a signature. Moreover, due to the sensitive nature of some parts of the questionnaire, the cover letter explicitly stated that *"some questions in the questionnaire might be difficult to answer, cause slight discomfort or might bring up difficult memories from your past or flight to Norway"*. It also included contact details to clinical back-up in the form of a psychiatrist at NKVTS, stating that participants could contact this person in order to receive information and support in accessing professional medical help in Norway. Out of hours and emergency service contact details were also included.

The address list provided by the Norwegian National Registry (NNR) included 1,235 addresses where the addressee was either not found or could not be reached. These potential participants were never found and therefore excluded from the study. Current rules for conducting research surveys in Norway prohibit more than one reminder being sent out to non-responders to encourage participation. Based on a small pilot project testing the use of telephone reminders with Arabic speaking personnel conducted on 530 non-responders in the sample, it was decided that telephone reminders would be used for all non-responders with an available telephone number (N = 5,675). Telephone contact was made with less than half of this group (N = 2,087). Table S1 in the supplementary material summarizes the answers given by this group when asked to participate. The telephone reminders were conducted in late March and early April, 2019. A postal reminder which included the questionnaire, the cover letter with informed consent and a prepaid return envelope was also sent out to non-responders who were not reached via telephone (N = 5,000). The postal reminder was sent out in early June, 2019. Figure 1 summarizes the flow of participants through REFUGE-I, and Table 1 provides comparative statistics on participants in REFUGE-I vs. the source and sample population. Of the initial 9,990 sampled individuals, 8,752 were reached either by post or telephone and 902 returned the questionnaire (response rate = 10.3% if non-contacts are excluded). Of the 902 responders, 665 (73.2%) were willing to take part in later waves of the study.

According to the original plan registered at ClinicalTrials.gov, data collection was planned to run for about 6-8 weeks. However, due to a very low response rate at the time of the planned closing date in mid January 2019, the study was extended, and the final closing date was in early September 2019. All procedures concerning the selection and recruitment of participants, including consent procedures, were approved by the Regional Committees for Medical and Health Research Ethics (REC) - Region South East (A) in Norway. Reference number 2017/1252.

Table 1. Demographic characteristics of participants vs. the source and sample populations

	Source population *N* = 14,350		Sample population *N* = 9,990		Participants *N* = 902		Participants willing to take part in subsequent surveys *N* = 665	
	n	(%)	*n*	(%)	*n*	(%)	*n*	(%)
Gender								
Female	5,117	(35.7)	3,552	(35.5)	320	(35.5)	236	(35.5)
Male	9,233	(64.3)	6,446	(64.5)	582	(64.5)	429	(64.5)
Age[1]								
18-29	6,135	(42.8)	4,265	(42.7)	197	(21.8)	148	(22.2)
30-39	4,769	(33.2)	3,315	(33.1)	310	(34.4)	218	(32.8)
40-49	2,263	(15.8)	1,604	(16.0)	230	(25.5)	173	(26.0)
50-64	1,034	(7.2)	721	(7.2)	145	(16.1)	112	(16.9)
>64	149	(1.0)	95	(1.0)	20	(2.2)	14	(2.1)
Civil status[1]								
Unmarried	5,879	(41.0)	4,047	(40.5)	236	(26.1)	176	(26.5)
Married	7,873	(54.8)	5,545	(55.5)	595	(66.0)	433	(65.1)
Other[2]	598	(4.2)	398	(4.0)	71	(7.9)	56	(8.4)
Year granted residency in Norway								
2015	2,993	(20.8)	2,081	(20.8)	N/A[3]		N/A[3]	
2016	7,513	(52.4)	5,267	(52.7)				
2017	3,844	(26.8)	2,652	(26.5)				

[1] Age and civil status for the two participating groups was based on participants' answers in the questionnaire.

[2] Includes widow(er), separated, divorced

[3] Individual-level data on the year residency was granted was not provided by the Norwegian National Registry.

METHODS

Quantitative analysis

Three waves of questionnaire surveys are planned for the REFUGE-study (REFUGE-I, II, and III). Collection for REFUGE-I has already been completed as described above. REFUGE-II and III are scheduled to be carried out roughly one and two years after REFUGE-I, respectively. The questionnaire used will be very similar for all three waves of the study. Key variables are highlighted in Table 2 below.

Table 2. Summary of key measures used in the longitudinal, three-wave, questionnaire survey

	Measure used[1]	Comments
Outcome variables		
Symptoms of PTSD	Harvard Trauma Questionnaire, HTQ	The first 16 items on trauma symptoms in section IV will be used
Symptoms of anxiety and depression	Hopkins Symptom Checklist, HSCL-25	The first 10 of the total 25 items will be used to measure symptoms of anxiety and the last 15 to measure symptoms of depression
Quality of life	World Health Organization Quality of Life assessment, WHOQOL-BREF	The scale consists of 26 items and all will be included
Somatic pain	Questions adapted from the Tromsø Study	10 questions will be used, 5 concerning muscle/joint pain and 5 concerning more general somatic pain
Perceived general health	European Social Survey	2 items from the scale will be included
Sleep difficulties	The Bergen Insomnia Scale	The scale consists of 6 items and all will be included
Predictor variables		
Potentially traumatic experiences *before* the flight from Syria (pre-migratory PTEs)	The Refugee Trauma History Checklist, RTHC	The scale consists of 8 items and all will be included
Potentially traumatic experiences *during* the flight from Syria (peri-migratory PTEs)	The Refugee Trauma History Checklist, RTHC	The scale consists of 8 items and all will be included
Post-migration stressful experiences	Post-migration stress scale	The scale consists of 24 items and all will be included
Social support	ENRICHD Social Support Inventory	The first 6 items of the scale will be included

[1] Further information on the measures used can be found in the ClinicalTrial.gov database where the study is registered (NCT03742128)

Qualitative analysis

In addition to the quantitative aspect of the REFUGE-study, qualitative analyses are also planned for future waves of the study, comprising interviews and focus group sessions. Questions regarding participation and non-participation will be included in interview guides. Further themes for the interview and focus group guides are in development, and directions will be refined as further findings emerge from the existing quantitative dataset.

Measures

In addition to the outcome variables listed in Table 2, the following measures are included in the questionnaire:

Integration

Previous research has highlighted that active participation in social contexts promotes mental health, quality of life and beneficial health behaviours[16–18]. The REFUGE-study approaches integration in agreement with the primary domains suggested by Ager and Strang[19], which are: employment and labour market, school and education attainments, housing, and health and health care. Furthermore, and in line with suggestions by Castles[20] and Niemi et al[21], we consider civic and social participation/social exclusion to be central indicators of refugees' access to and active involvement in important spheres of the host societies, and these markers thus indicate a central component of social capital[22].

Therefore, in the first data wave, measures of integration, conceptualized as registry measures of education, work and school participation, sick leave and other health-related registry data, are included. Social integration is explored through measures of post migratory stress (e.g. "Often felt excluded or isolated in the Norwegian society", "Often being unable to buy necessities"), social support and quality of life. In the coming data collection waves, a scale measuring social participation will also be included. This scale will be incorporated both in the quantitative part of the study and as a specific topic within the planned qualitative interviews and focus groups. Furthermore, when data collection waves 2 and 3 are completed, the bidirectional interaction between mental health and integration over time will be investigated.

Outcomes

Complementary to the Harvard Trauma Questionnaire, an item is included regarding re-experiencing traumatic events or intrusive memories, which asks whether the participant experiences this, how often, and how distressing this is. Also included in the questionnaire is an item on daily effects of chronic physical illness, disability, infirmity or mental health problem/s.

Predictors

In addition to the predictors listed in Table 2, the survey includes questions regarding violence and threats experienced since the participant's arrival in Norway, such as physical violence, threats, and theft. As an addition to the social support scale (ESSI), 3 items have been included to assess how easily the respondent can get help from neighbours, how many people the participant can count on when serious problems occur, and how much concern people show in what the respondent is doing.

Sociodemographics

Important background and demographic variables include: gender, age, marital status, number of children, refugee status upon arrival (i.e. asylum seeker, quota refugee, family reunion, or other), whether the participant fled Syria alone or with a partner, family and/or friends, whether other family members had already settled in Norway prior to refugee's arrival in the country, time elapsed between when a participant fled Syria and arrived in Norway, and time in Norway prior to participating in the study. Tables 3 and 4 provide descriptive statistics on participants on the aforementioned variables from the first wave of data collection. The number of participants with missing values across variables can be interpreted from the table (applies for all tables).

Additional sociodemographic data collected include: smoking; alcohol and drug use; employment status (*Do you currently hold paid employment in Norway? Yes/No)*; job satisfaction; self-reported competence in English and Norwegian language; and years of education completed (*How many years of schooling do you have? No education/1-5 years/6-9 years/10-12 years/More than 12 years)*. Further details on the scales used, their psychometric properties and how variables will be handled in analyses can be found in the ClinicalTrials.gov database (NCT03742128).

Table 3. Descriptive statistics on participating refugees from Syria

	Participants, *N* = 902		Participants willing to take part in longitudinal questionnaire survey, *N* = 665	
	n	(%)	*n*	(%)
Number of children				
I do not have children	271	(31.6)	213	(33.5)
1	63	(7.4)	44	(6.9)
2	125	(14.6)	86	(13.5)
3	139	(16.2)	103	(16.2)
4	101	(11.8)	78	(12.3)
5	77	(9.0)	53	(8.3)
6 or more	81	(9.5)	59	(9.3)
Total	857	(100.0)	636	(100.0)
Education[3]				
9 years or less	394	(44.7)	281	(43.0)
10-12 years	158	(17.9)	116	(17.8)
More than 12 years	330	(37.4)	256	(39.2)
Total	882	(100.0)	653	(100.0)
Refugee status upon arrival				
Asylum seeker	454	(52.5)	325	(51.0)
Quota refugee	273	(31.6)	209	(32.8)
Family reunion	133	(15.4)	100	(15.7)
Other	4	(0.5)	3	(0.5)
Total	864	(100.0)	637	(100.0)
Arrived in Norway...				
…alone	247	(28.1)	182	(28.0)
…with friends, but no family	56	(6.4)	43	(6.6)
…with family	576	(65.5)	425	(65.4)
Total	879	(100.0)	650	(100.0)
Family member previously settled in Norway				
No	594	(68.3)	440	(68.4)
Yes	276	(31.7)	203	(31.6)
Total	870	(100.0)	643	(100.0)
Length of flight[1]				
Less than 3 months	165	(33.7)	124	(33.9)
3 to 12 months	61	(12.4)	42	(11.5)
1 to 2 years	59	(12.0)	43	(11.7)
2 to 3 years	77	(15.7)	56	(15.3)
More than 3 years	128	(26.1)	101	(27.6)
Total	490	(100.0)	366	(100.0)
Residency time in Norway[2]				
Less than 2 years	104	(16.8)	83	(17.9)
Between 2 and 3 years	151	(24.4)	120	(25.9)
Between 3 and 4 years	289	(46.7)	209	(45.1)
More than 4 years	75	(12.1)	51	(11.0)
Total	619	(100.0)	463	(100.0)

[1] Estimated through the number of days elapsed between a refugee reportedly left Syria and arrived in Norway
[2] Estimated through the number of days elapsed between a refugee reportedly arrived in Norway and the date he/she returned the questionnaire

Table 4. Potentially traumatic experiences prior to and during the flight from Syria among participants

		Participants *N* = 902[1]		Participants willing to take part in longitudinal survey *N* = 665[1]	
		n	(%)	*n*	(%)
***Before* you left your home, have you personally faced any of the following situations or events:**					
War at close quarters	No	41	(4.7)	31	(4.8)
	Yes	840	(95.3)	618	(95.2)
Forced separation from family or close friends	No	324	(40.3)	235	(39.8)
	Yes	480	(59.7)	355	(60.2)
Loss or disappearance of family member(s) or loved one(s)	No	287	(35.3)	213	(35.5)
	Yes	526	(64.7)	387	(64.5)
Physical violence or assault	No	554	(70.5)	400	(69.3)
	Yes	232	(29.5)	177	(30.7)
Witnessing physical violence or assault	No	304	(36.9)	203	(33.5)
	Yes	520	(63.1)	403	(66.5)
Torture	No	567	(72.8)	410	(71.6)
	Yes	212	(27.2)	163	(28.4)
Sexual violence	No	710	(93.3)	518	(92.7)
	Yes	51	(6.7)	41	(7.3)
Other frightening situation(s) where you felt your life was in danger	No	103	(12.0)	74	(11.7)
	Yes	754	(88.0)	561	(88.3)
***After* you left your home, during your flight, have you personally faced any of the following situations or events:**					
War at close quarters	No	408	(49.3)	310	(50.7)
	Yes	420	(50.7)	302	(49.3)
Forced separation from family or close friends	No	412	(52.5)	298	(51.5)
	Yes	373	(47.5)	281	(48.5)
Loss or disappearance of family member(s) or loved one(s)	No	422	(53.8)	312	(53.6)
	Yes	362	(46.2)	270	(46.4)
Physical violence or assault	No	638	(83.6)	467	(83.5)
	Yes	125	(16.4)	92	(16.5)
Witnessing physical violence or assault	No	566	(72.6)	405	(70.7)
	Yes	214	(27.4)	168	(29.3)
Torture	No	657	(86.8)	481	(87.1)
	Yes	100	(13.2)	71	(12.9)
Sexual violence	No	722	(97.3)	529	(97.2)
	Yes	20	(2.7)	15	(2.8)
Other frightening situation(s) where you felt your life was in danger	No	350	(42.8)	258	(42.9)
	Yes	468	(57.2)	344	(57.1)

[1] Not all participants answered all items, therefore, the total number of answers for a given item may be less than 902 and 665 for the two groups, respectively.

The administration and logistics of the survey was handled by the research and consulting firm, Ipsos, which has extensive experience with and infrastructure for these types of surveys. Ipsos is also responsible for securely storing participants' Norwegian identity numbers so that longitudinal tracking of individuals and linking to registry data is possible. The identity numbers are unknown to all researchers involved.

Registry data

As part of the consent procedure, the cover letter explained that participation in the study entailed that questionnaire data would be linked to registry data in the following Norwegian registries: National education database, NUDB (provides education statistics on an individual level from 1970 up until the present); employment and sick-leave databases (contain individual level data on work-participation and doctor-certified sickness absence from work); Norwegian Prescription Database, NorPD (contains individual level data on all prescription drugs dispensed by pharmacies in Norway); the KUHR database (contains individual level data on the utilization of primary health care services in Norway - e.g. primary care doctors and physiotherapists); and the Norwegian Patient Registry, NPR (contains individual level data on the utilization of specialized health care in Norway).

Patient and public involvement

The REFUGE-study was supported throughout the development process by members of the community. Focus groups were held in the early stages of development in order to tailor the questionnaire, and a user reference group was created in order to act as an advisory group, providing insight during the planning, development and implementation stages. Community members were also involved in the recruitment process, providing insight and advice on the dissemination of information about the study through social media.

Findings to date

The first wave of data collection in Norway has been completed. At the time of writing, no findings have been published.

Strengths and limitations

The REFUGE-study has several important strengths, both in terms of methodology, and in value of the resulting data. Firstly, the study population was randomly selected from a large source population consisting of all adult refugees from Syria residing in Norway who met the

study's eligibility criteria, obtained from the Norwegian National Registry. In comparison, many of the previous studies on mental health in refugee populations rely on convenience sampling. Further, the use of a three-wave longitudinal survey design will allow for better exploration of cause-effect relationships between variables in the study, than purely cross-sectional data. In addition, research on the association between refugee mental health and integration is scarce. By linking longitudinal questionnaire data to registry data on education-, work- and health-related parameters, the study could make important contributions to the dearth of evidence on this topic. Also, combining self-report data with registry data from well-established national registries may reduce common method bias. Research on refugee mental health to date relies heavily on self-report data. A further strength of the study is that most of the key variables are measured using well-documented and validated scales. Review articles on refugee mental health frequently highlight the large degree of variance in terms of methods used, and call for increased focus on methodological issues. Lastly, the close collaboration between the REFUGE-study group in Norway and its main collaborating partner, the Red Cross University College in Sweden, will offer ample opportunities to compare Syrian refugee populations in two different countries, as both projects use similar measures and have agreed to collaborate on and combine datasets.

An important potential weakness of REFUGE-I is that less than 11 percent of the sampled population participated in the study. This could lead to selection bias problems. As can be seen from Table 1, participants are very similar to the source and sample population in terms of gender, though the proportion of young and unmarried refugees are notably smaller in the participating group. Table S2 in the supplementary material shows that the geographical distribution across Norway's 18 counties was very similar for participants and the sample population. In terms of residency status, participants had the same proportional breakdown as the sample population: 95% had temporary residency in Norway at the time of the survey and 5% had permanent residency (result not shown in tables). In order to further explore selection bias, we investigated whether there were any trends across demographic and background variables in terms of when the surveys were filled out and returned. Given that the survey was open for nine months, exploring the timing of participation may give some indication of different groups' willingness to participate, and, by extension, suggest which groups may be over- and underrepresented among participants. . While the most common reason for non-participation was unwillingness, a potentially significant contributing factor to the low participation rate may be the presence of low literacy rates within the sampled population. As

shown in Figure 1, 49 participants stated an inability to read Arabic to explain non-participation, and it is conceivable that this was the case for a number of sampled individuals who failed to return the survey. Regrettably, current ethical laws in Norway do not allow for an online-based questionnaire where Arabic voice-over could be utilized. Therefore, potential participants with low reading and writing proficiency regrettably were effectively excluded.

Table S3 in the supplementary material shows the distribution of demographic variables across 4 different time-periods of participation (i.e. the 9-month period the survey was open was divided into 4 shorter periods), and Table S4 shows the distribution across background characteristics related to refugee status and history. Differences in distributions across time-periods were tested with chi-square test of equal proportion. As can be seen from the tables, there was weak or no evidence that the timing of participation was related to demographic and/or background variables with three exceptions. First, there was very clear evidence that residency time in Norway was negatively associated with early participation - i.e. the longer a refugee's residency time in Norway, the less likely (s)he was to participate in the first time-periods following study launch ($p < 0.001$), relatively speaking. There was also very strong statistical evidence ($p < 0.001$) that pre-migratory stress was associated with the timing of participation, though the underlying trend was not easily interpretable. Refugees with the highest number of potentially traumatic pre-flight experiences (PTEs) were more likely to participate in the early periods after study launch (relatively speaking). This was not true, however, for the refugee group with the second to most PTEs. Lastly, there was moderate evidence that refugee status upon arrival was association with the timing of participation ($p = 0.01$), though no clear underlying pattern was evident.

Another limitation of the present study is the survey design used to attain prevalences of depression, anxiety and PTSD symptoms. Short-form questionnaires, while efficient, do not capture all aspects of the measured constructs. Additionally, recent studies have suggested that when self-report measures are used, resulting prevalences tend to be higher than when using diagnostic interviews[23,24]. However, the questionnaires used in the current study to measure PTSD, anxiety and depression have been validated for use within the studied population and their use allows for many more participants to be reached, improving the generalizability of the findings.

Perhaps the most significant learning opportunity provided by the present study thus far has been the challenging recruitment process. Although extensive recruitment efforts were

employed, the participation rate for REFUGE-I was just above 10%. As noted previously, methods to boost recruitment involved the utilisation of contacts within the community, dedicated Facebook and web pages in Arabic, and Q&A sessions held at Adult Education centres in Norway's major cities, as well as the dissemination of information about the project online through purpose-built, animated videos and newsletters. Researchers aiming to gather data from similar populations would do well to ensure that sufficient time and resources are dedicated to the recruitment phase of the study.

Future plans

The REFUGE-cohort study will conduct a second wave of data collection in 2020. A third wave of data collection is planned in 2021, pending funding. Furthermore, we plan to link questionnaire data to Norwegian registry data after all three waves of data collection have been completed. Registry data will be obtained for time-periods both prior to and after the three-wave survey. Primary and secondary objectives with detailed plans for analyses for studies involving registry data will be registered at ClinicalTrials.gov prior to obtaining the registry data, so that true hypothesis-testing studies from the REFUGE-cohort are distinguishable from more exploratory and data-driven studies. Finally, pending ethics approval, we will begin the process of merging the Norwegian REFUGE-cohort with existing datasets in Sweden, creating the REFUGE-database.

Parallel to completing the survey data collection, data-merging and registry data obtainment, we aim to publish papers in accordance with our pre-registered publication plan at ClinicalTrials.gov.

COLLABORATION

We welcome potential collaboration with other research groups. Interested researchers should contact the REFUGE research group for collaboration and knowledge-sharing. Locally collected data can then be added to the REFUGE-database. Reference estimates (e.g. prevalence, incidence and associations) can then be continuously updated and made available to researchers abiding by the EU's GDPR laws and regulations. In addition, the REFUGE-database will also include data obtained through Scandinavian social and health-registries.

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Data availability: Deidentified participant data will be made available for reuse upon reasonable request pending ethics approval, compliance with the General Data Protection Regulation (GDPR), and discretion of the research group with regard to the prospective research project proposal. Requests should be sent to refuge@nkvts.no. Additional information regarding the scales used, statistical analysis plans and future data collection is available through ClinicalTrials.gov (NCT03742128).

Figure legend:

Figure 1: Flowchart of participants through the study.

[1] Refugees were either resettlement/quota refugees; asylum seekers who were granted asylum in Norway; or individuals coming through the program *Family immigration with a person who has protection (asylum) in Norway*. The source population was identified through the Norwegian National Registry (NNR)

[2] Information was obtained when non-responders were contacted during the telephone reminder

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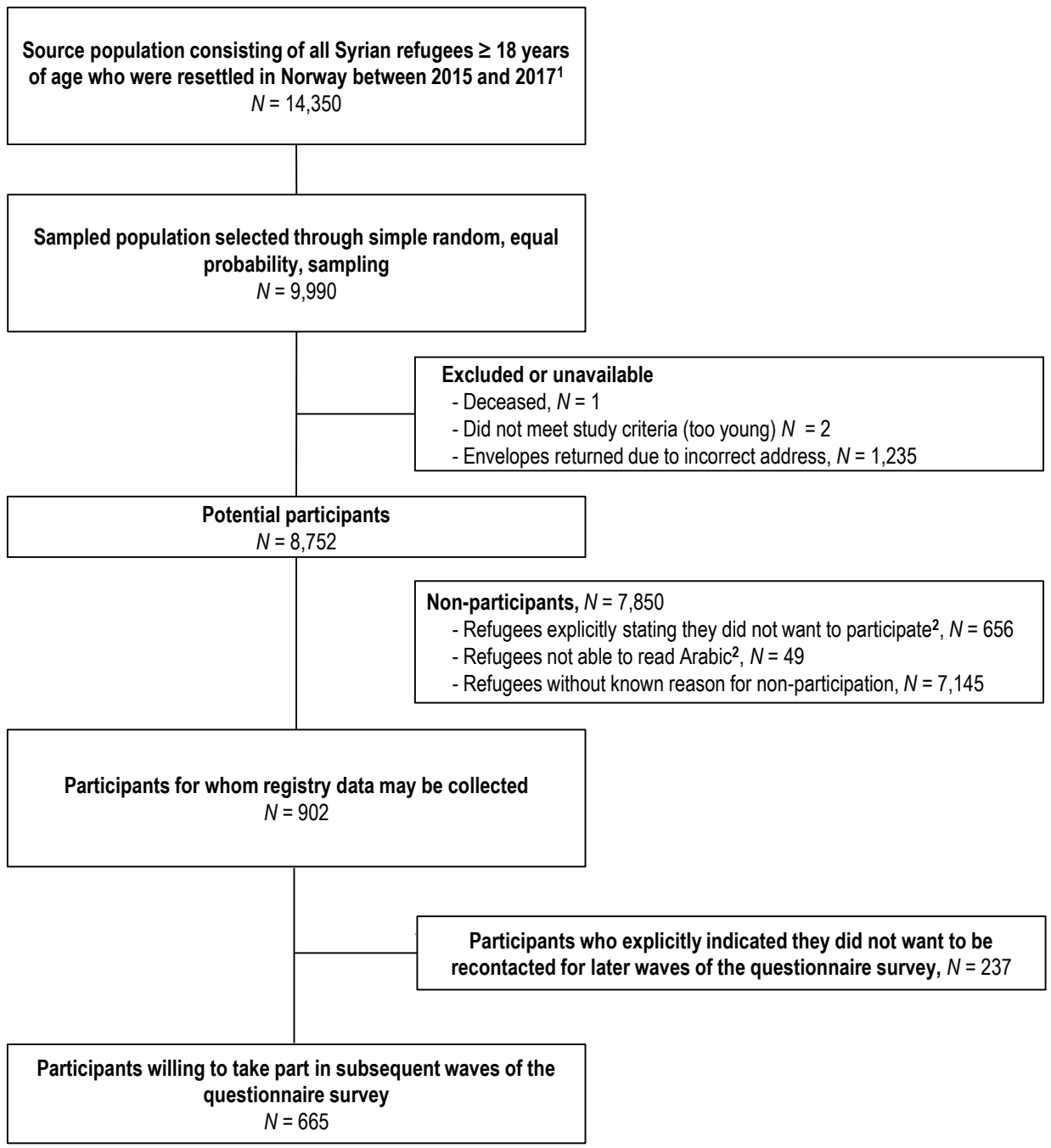
Source population consisting of all Syrian refugees ≥ 18 years of age who were resettled in Norway between 2015 and 2017[1]
N = 14,350
Sampled population selected through simple random, equal probability, sampling
N = 9,990
Excluded or unavailable
- Deceased, N = 1
- Did not meet study criteria (too young) N = 2
- Envelopes returned due to incorrect address, N = 1,235
Potential participants
N = 8,752
Non-participants, N = 7,850
- Refugees explicitly stating they did not want to participate[2], N = 656
- Refugees not able to read Arabic[2], N = 49
- Refugees without known reason for non-participation, N = 7,145
Participants for whom registry data may be collected
N = 902
Participants who explicitly indicated they did not want to be recontacted for later waves of the questionnaire survey, N = 237
Participants willing to take part in subsequent waves of the questionnaire survey
N = 665

Table S1. Responses given by initial non-responders during telephone reminder sessions (N = 2,087)

	N	(%)
Answers given by refugees		
Would like to participate and does not need a new questionnaire	403	(19.1)
Would like to participate and needs a new questionnaire	856	(40.8)
Does not want to participate	656	(30.8)
Moved and wants a new questionnaire	69	(3.3)
Moved and does not want a new questionnaire	29	(1.4)
Wrong number/person	25	(1.2)
Does not understand Arabic	49	(2.4)
Total	2,087	(100.0)

Table S2. Geographical distribution across Norway's 18 counties for participants and sample population of refugees from Syria

	Sample population N = 9,990		Participants N = 902	
	n	(%)	n	(%)
Akershus	703	(7.0)	52	(5.7)
Aust-Agder	347	(3.5)	30	(3.3)
Buskerud	470	(4.7)	39	(4.3)
Finnmark	254	(2.5)	23	(2.6)
Hedmark	311	(3.1)	30	(3.3)
Hordaland	1,009	(10.1)	88	(9.8)
Møre og Romsdal	486	(4.9)	51	(5.7)
Nordland	670	(6.7)	65	(7.2)
Oppland	381	(3.8)	37	(4.1)
Oslo	773	(7.7)	70	(7.9)
Rogaland	831	(8.3)	63	(7.0)
Sogn og Fjordane	380	(3.8)	34	(3.8)
Telemark	398	(4.0)	40	(4.4)
Troms	449	(4.5)	51	(5.7)
Trøndelag	1,049	(10.5)	96	(10.5)
Vest-Agder	520	(5.2)	50	(5.5)
Vestfold	475	(4.8)	44	(4.9)
Østfold	484	(4.9)	39	(4.3)
Total	9,990	(100.0)	902	(100.0)

Table S3. Demographic characteristics of participating refugees from Syria according to when they returned the questionnaire

	4th quarter 2018		1st quarter 2019		2nd quarter 2019		3rd quarter 2019		Total		Chi-square
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	
Gender											0.08
Male	278	(64.2)	66	(69.5)	157	(68.0)	77	(55.8)	578	(64.4)	
Female	155	(35.8)	29	(30.5)	74	(32.0)	61	(44.2)	319	(35.6)	
Total	433	(100.0)	95	(100.0)	231	(100.0)	138	(100.0)	897	(100.0)	
Age groups											0.36
18-29	87	(20.1)	28	(29.5)	50	(21.6)	31	(22.5)	196	(21.9)	
30-39	142	(32.8)	28	(29.5)	88	(38.1)	50	(36.2)	308	(34.3)	
40-49	122	(28.2)	19	(20.0)	52	(22.5)	36	(26.1)	229	(25.5)	
50-64	72	(16.6)	19	(20.0)	37	(16.1)	16	(11.6)	140	(15.6)	
>64	10	(2.3)	1	(1.0)	4	(1.7)	5	(3.6)	24	(2.7)	
Total	433	(100.0)	95	(100.0)	231	(100.0)	138	(100.0)	897	(100.0)	
Civil status											0.10
Unmarried	121	(27.9)	31	(32.6)	60	(26.0)	22	(15.9)	234	(26.1)	
Married	276	(63.7)	58	(61.1)	154	(66.7)	104	(75.4)	592	(66.0)	
Other[1]	36	(8.3)	6	(6.3)	17	(7.4)	12	(8.7)	71	(7.9)	
Total	433	(100.0)	95	(100.0)	231	(100.0)	138	(100.0)	897	(100.0)	
Education											0.53
9 years or less	187	(44.4)	38	(42.2)	111	(48.7)	53	(38.4)	389	(44.4)	
10-12 years	74	(17.6)	18	(20.0)	35	(15.4)	31	(22.5)	158	(18.0)	
More than 12 years	160	(38.0)	34	(37.8)	82	(36.0)	54	(39.1)	330	(37.6)	
Total	421	(100.0)	90	(100.0)	228	(100.0)	138	(100.0)	877	(100.0)	

[1] Includes: divorced, widow(er), separated

Table S4. Refugee and migratory characteristics of participating refugees from Syria according to when they returned the questionnaire

	4th quarter 2018		1st quarter 2019		2nd quarter 2019		3rd quarter 2019		Total		Chi-square
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	
Ref. status upon arrival											0.01
Asylum seeker	208	(50.5)	54	(61.4)	122	(54.7)	66	(48.5)	450	(52.4)	
Quota refugee	147	(35.7)	20	(22.7)	70	(31.4)	35	(25.7)	272	(31.7)	
Family reunion	55	(13.3)	14	(15.9)	31	(13.9)	33	(24.3)	133	(15.5)	
Other	2	(0.5)	0	(0.0)	0	(0.0)	2	(1.5)	4	(0.5)	
Total	412	(100.0)	88	(100.0)	223	(100.0)	136	(100.0)	859	(100.0)	
Arrived in Norway...											0.47
...alone	121	(28.8)	30	(32.6)	64	(28.1)	31	(23.0)	246	(28.1)	
...with friends only	31	(7.4)	7	(7.6)	11	(4.8)	7	(5.2)	56	(6.4)	
...with family	268	(63.8)	55	(59.8)	153	(67.1)	97	(71.9)	573	(65.5)	
Total	420	(100.0)	92	(100.0)	228	(100.0)	135	(100.0)	875	(100.0)	
Length of flight											0.58
Less than 3 months	73	(31.2)	20	(39.2)	42	(33.6)	30	(37.5)	165	(33.7)	
3 to 12 months	24	(10.3)	6	(11.8)	17	(13.6)	14	(17.5)	61	(12.4)	
1 to 2 years	31	(13.2)	7	(13.7)	15	(12.0)	6	(7.5)	59	(12.0)	
2 to 3 years	34	(14.5)	7	(13.7)	22	(17.6)	14	(17.5)	77	(15.7)	
More than 3 years	72	(30.8)	11	(21.6)	29	(23.2)	16	(20.0)	128	(26.1)	
Total	234	(100.0)	51	(100.0)	125	(100.0)	80	(100.0)	490	(100.0)	
Residency time in Norway											<0.001
Less than 2 years	69	(22.9)	12	(18.5)	16	(10.3)	7	(7.2)	104	(16.8)	
2-3 years	73	(24.3)	14	(21.5)	38	(24.4)	26	(26.8)	151	(24.4)	
3-4 years	140	(46.5)	32	(49.2)	76	(48.7)	41	(42.3)	289	(46.7)	
More than 4 years	19	(6.3)	7	(10.8)	26	(16.7)	23	(23.7)	75	(12.1)	
Total	301	(100.0)	65	(100.0)	156	(100.0)	97	(100.0)	619	(100.0)	
PTEs before flight[1]											<0.001
0-1	34	(7.9)	10	(10.6)	34	(14.8)	15	(11.3)	93	(10.5)	
2-3	101	(23.4)	25	(26.6)	86	(37.4)	29	(21.8)	241	(27.1)	
4-5	185	(42.9)	34	(36.2)	75	(32.6)	64	(48.1)	358	(40.3)	
>5	111	(25.8)	25	(26.6)	35	(15.2)	25	(18.8)	196	(22.1)	
Total	431	(100.0)	94	(100.0)	230	(100.0)	133	(100.0)	888	(100.0)	
PTEs during flight[1]											0.46
0-1	154	(36.8)	31	(34.1)	96	(42.7)	54	(41.9)	335	(38.8)	
2-3	143	(34.2)	32	(35.1)	71	(31.6)	33	(25.6)	279	(32.3)	
4-5	89	(21.3)	19	(20.9)	48	(21.3)	32	(24.8)	188	(21.8)	
>5	32	(7.7)	9	(9.9)	10	(4.4)	10	(7.7)	61	(7.1)	
Total	418	(100.0)	91	(100.0)	225	(100.0)	129	(100.0)	863	(100.0)	

[1] All individuals with at least one answered item on the PTE-scale were given a sum-score for total PTEs before/during flight

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Cohort profile: Resettlement in Uprooted Groups Explored (REFUGE) – A longitudinal study of mental health and integration in adult refugees from Syria resettled in Norway between 2015 and 2017

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Cohort profile: Resettlement in Uprooted Groups Explored (REFUGE) – A longitudinal study of mental health and integration in adult refugees from Syria resettled in Norway between 2015 and 2017

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ABSTRACT

Purpose: In the field of forced migration and mental health research, longitudinal studies with large sample sizes and rigorous methodology are lacking. Therefore, the REFUGE-study was initiated in order to enhance current knowledge on mental health, quality of life and integration among adult refugees from Syria resettled in Norway. The main aims of the study are to investigate risk and protective factors for mental ill health in a longitudinal perspective; to trace mental health trajectories and investigate important modifiers of these trajectories; and to explore the association between mental health and integration in the years following resettlement. The aims will be pursued by combining data from a longitudinal, three-wave questionnaire survey with data from population-based registries on education; work participation and sick-leave; health-care utilization; and drug prescription. The goal is to incorporate the data in an internationally shared database, the REFUGE-database, where collaborating researchers may access and use data from the study as well as deposit data from similar studies.

Participants: Adult (≥ 18 years), Syrian citizens who arrived in Norway as quota refugees, asylum seekers or through Norway's family reunion program between January 1, 2015 and December 31, 2017. Of the initial 9,990 sampled individuals for the first wave of the study (REFUGE-I), 8,752 were reached by post or telephone and 902 responded (response rate = 10.3%).

Findings to date: None published

Future plans: The REFUGE-cohort study will conduct two additional data collections (2020 and 2021). Furthermore, questionnaire data will be linked to population-based registries after all three waves of data collection have been completed. Registry data will be obtained for time-periods both prior to and after the survey data collection points. Finally, pending ethics approval, we will begin the process of merging the Norwegian REFUGE-cohort with existing datasets in Sweden, establishing the extended REFUGE-database.

Registration: ClincalTrials.gov database (NCT03742128).

Strengths and Limitations

- The study features a large sample of both male and female adult refugees from Syria who were resettled in a high-income country between 2015 and 2017.
- Study participants were selected through random sampling from a population-based source population identified using Norway's National Registry – i.e. all refugees from Syria residing in Norway who met inclusion criteria had equal probability of selection.
- The study will use a three-wave survey design which will enable longitudinal tracking of self-reported mental health and other key measures
- The study will link data from the three-wave, questionnaire survey to data in Norway's large, population-based registries on education, work participation and sick-leave, health-care utilization and drug prescription; as well as to other datasets/data sources within the EU.
- Initial data collection yielded a low response rate, despite extensive recruitment efforts.

INTRODUCTION

The adversities of forced migration make the current population of more than 70 million forcibly displaced people especially vulnerable[1]. Here, the concept of "vulnerability" refers to refugees' heightened exposure to potentially traumatic events (PTEs) such as torture, war and/or violence-related traumas prior to or during forced migration, as well as experiences of post-migration socioeconomic hardships and social isolation. Together, these risk factors create a vulnerability that constitutes a profound risk for mental ill health and reduced quality of life with potential long-lasting effects[2–4].

Given the aforementioned high burden of mental ill health in refugee populations and the centrality of *functional impairment* in the diagnostic frameworks for PTSD, anxiety and depression in the main diagnostic manuals[5,6], few studies have looked at integration in relation to mental health within refugee populations. The studies available show that general health problems, as well as symptoms of PTSD and depression, are adversely associated with economic and social integration[7,8], with one study finding mental health to be a mediator between post-migration stressors and integration[9]. Still, longitudinal studies with large sample sizes and rigorous methodology are lacking and the socio-political controversy that is linked to the topic of refugee health often influences the measures and investigative methods used[10]. Therefore, studies that bridge these gaps are warranted in order to better understand the resettlement stressors and the mental health burden of refugees resettled in a host country in order to inform policy and practice.

Accordingly, the REFUGE-study was initiated in order to enhance current knowledge on mental health and quality of life among adult refugees from Syria resettled in Norway following the 2011 outbreak of the civil war in Syria. The main aims of the study are to investigate risk and protective factors for mental ill health in a longitudinal perspective; to trace mental health trajectories and investigate important modifiers of these trajectories; and to explore the association between mental health and integration in the years following resettlement. This will be done through a planned longitudinal, three-wave survey design linked to population-based registries in Norway on education; work participation and sick-leave; health-care utilization; and drug prescription.

A broader, secondary aim is to extend the REFUGE-study beyond Norway's borders, through collaboration between the REFUGE-study group in Norway and partner institutions in Sweden and the United Kingdom, forming the REFUGE-consortium. This work, pending

ethics approval, will include setting up and servicing a shared database in order to harness the research potential that lies within the existing datasets on resettled refugees from Syria in Norway and Sweden (N > 4,500).

A tertiary, long-term goal is to further expand the REFUGE-database by encouraging researchers in other countries to complete similar, nation-wide data-collections that can be added to the existing database. In turn, given the extensive number of included participants, the REFUGE-database will have ample opportunities to provide unique cross-country, intersectional, comparative analyses that can provide robust explanatory models of refugees' health and social outcomes, in turn informing social policy and practice.

At the time of writing this cohort profile, the first wave of the three-wave survey design has been completed. The REFUGE-study is registered in the ClincalTrials.gov database (NCT03742128).

COHORT DESCRIPTION

Setting

The study is set in Norway, a high-income country, with a population of 5.3 million people[11]. Approximately 4.5% of the Norwegian population has a refugee background[12].The Directorate of Immigration (UDI) is the central agency in the Norwegian immigration administration. UDI facilitates lawful immigration and administrates applications for residency and citizenship, including asylum applications[for details, please see 13]. Since its onset in 2011, the civil war in Syria has forced more than 6.5 million Syrian citizens to flee the country as refugees, of which an estimated one million have reached Europe, excluding Turkey[14,15]. At the time of primary data collection, forced migrants from Syria therefore constituted the largest group of newly resettled refugees and asylum-seekers in Norway.

Eligibility

The source population for the REFUGE-study cohort was defined by the following three criteria: Potential participants had to be (1) Syrian citizens who arrived in Norway as either a resettlement refugee (quota refugee), an asylum seeker, or through Norway's family reunion program, (2) granted permanent or temporary residency and registered with an address in

Norway between January 1, 2015 and December 31, 2017, and finally, (3) 18 years of age or older at the time the sample was drawn from the source population.

These criteria were sent to the Norwegian National Registry (NNR) who generated a list of potential participants (N = 14,350) from their database consisting of all individuals residing in Norway at that time. A simple, random, equal probability sample of 9,990 Syrian citizens was then drawn in August, 2018.

Study preparation and promotion

In initial stages of development, approximately a year before the commencement of the data collection, an early version of the questionnaire was tested in a reception centre. Arabic speaking asylum seekers filled out the survey and participated in focus groups with the aim of testing and tailoring the questionnaire for length, comprehension and cultural sensitivity. Several amendments to the questionnaire then followed as a result of the feedback obtained in these focus groups. Findings from this preliminary stage also prompted the creation of a user reference-group, consisting of six Syrians living in Norway. This user reference-group served as an advisory board throughout the planning, development and implementation of the study.

Additionally, prior to data collection, a number of strategies were employed in order to inform potential participants about the study and boost participation. Key persons within the community were identified and contacted in order to discuss ways to explain and promote the study through social media and other channels. Based on input from these sources, several short, animated movies were made in Arabic in order to explain why the study was being undertaken, what participation entailed, and how key issues in research, such as informed consent, confidentiality, data handling, and privacy rights, would be handled. REFUGE web and Facebook pages were also created in both Arabic and Norwegian, conveying the same information as the movies, in more detail. The Facebook page, with Q&A, was continuously supervised and moderated by a native Arabic speaker.

In order to reach a wider range of potential participants, in-person and paper-based dissemination of information also took place. Information and Q&A sessions at Adult Education centers (VOs) in Norway's larger cities were held by the REFUGE team members, including an Arabic interpreter from Syria who was involved in the study from the beginning. Information about the study was also sent to local community refugee centers throughout

Norway. These centers work with refugees on a daily basis, assisting and counselling them on various matters related to the integration process into Norway.

Sampling

The first wave of the REFUGE-study (REFUGE-I) was launched at the end of November 2018. Each of the 9,990 sampled Syrian refugees were sent an envelope containing the study questionnaire, a cover letter in Arabic and a prepaid return envelope. The cover letter explained the purpose and voluntary nature of the study, what participation entailed, and issues surrounding confidentiality and data handling. It also included a space for willing participants to provide written informed consent in the form of a signature. Moreover, due to the sensitive nature of some parts of the questionnaire, the cover letter explicitly stated that *"some questions in the questionnaire might be difficult to answer, cause slight discomfort or might bring up difficult memories from your past or flight to Norway"*. It also included contact details to clinical back-up in the form of a psychiatrist at NKVTS, stating that participants could contact this person in order to receive information and support in accessing professional medical help in Norway. Out of hours and emergency service contact details were also included.

The address list provided by the Norwegian National Registry (NNR) included 1,235 addresses where the addressee was either not found or could not be reached. These potential participants were never found and therefore excluded from the study. Current rules for conducting research surveys in Norway prohibit more than one reminder being sent out to non-responders to encourage participation. Based on a small pilot project testing the use of telephone reminders with Arabic speaking personnel conducted on 530 non-responders in the sample, it was decided that telephone reminders would be used for all non-responders with an available telephone number (N = 5,675). Telephone contact was made with less than half of this group (N = 2,087). Table S1 in the supplementary material summarizes the answers given by this group when asked to participate. The telephone reminders were conducted in late March and early April, 2019. A postal reminder which included the questionnaire, the cover letter with informed consent and a prepaid return envelope was also sent out to non-responders who were not reached via telephone (N = 5,000). The postal reminder was sent out in early June, 2019. Figure 1 summarizes the flow of participants through REFUGE-I, and Table 1 provides comparative statistics on participants in REFUGE-I vs. the source and sample population. Of the initial 9,990 sampled individuals, 8,752 were reached either by post

or telephone and 902 returned the questionnaire (response rate = 10.3% if non-contacts are excluded). Of the 902 responders, 665 (73.2%) were willing to take part in later waves of the study.

According to the original plan registered at ClinicalTrials.gov, data collection was planned to run for about 6-8 weeks. However, due to a very low response rate at the time of the planned closing date in mid-January 2019, the study was extended, and the final closing date was in early September 2019. All procedures concerning the selection and recruitment of participants, including consent procedures, were approved by the Regional Committees for Medical and Health Research Ethics (REC) - Region South East (A) in Norway. Reference number 2017/1252.

The administration and logistics of the survey was handled by the research and consulting firm, Ipsos, which has extensive experience with and infrastructure for these types of surveys. Ipsos is also responsible for securely storing participants' Norwegian identity numbers so that longitudinal tracking of individuals and linking to registry data is possible. The identity numbers are unknown to all researchers involved.

Table 1. Demographic characteristics of participants vs. the source and sample populations

	Source population *N* = 14,350		Sample population *N* = 9,990		Participants *N* = 902		Participants willing to take part in subsequent surveys *N* = 665	
	n	(%)	*n*	(%)	*n*	(%)	*n*	(%)
Gender								
Female	5,117	(35.7)	3,552	(35.5)	320	(35.5)	236	(35.5)
Male	9,233	(64.3)	6,446	(64.5)	582	(64.5)	429	(64.5)
Age[1]								
18-29	6,135	(42.8)	4,265	(42.7)	197	(21.8)	148	(22.2)
30-39	4,769	(33.2)	3,315	(33.1)	310	(34.4)	218	(32.8)
40-49	2,263	(15.8)	1,604	(16.0)	230	(25.5)	173	(26.0)
50-64	1,034	(7.2)	721	(7.2)	145	(16.1)	112	(16.9)
>64	149	(1.0)	95	(1.0)	20	(2.2)	14	(2.1)
Civil status[1]								
Unmarried	5,879	(41.0)	4,047	(40.5)	236	(26.1)	176	(26.5)
Married	7,873	(54.8)	5,545	(55.5)	595	(66.0)	433	(65.1)
Other[2]	598	(4.2)	398	(4.0)	71	(7.9)	56	(8.4)
Year granted residency in Norway								
2015	2,993	(20.8)	2,081	(20.8)	N/A[3]		N/A[3]	
2016	7,513	(52.4)	5,267	(52.7)				
2017	3,844	(26.8)	2,652	(26.5)				

[1] Age and civil status for the two participating groups was based on participants' answers in the questionnaire.

[2] Includes widow(er), separated, divorced

[3] Individual-level data on the year residency was granted was not provided by the Norwegian National Registry.

METHODS

Quantitative measures

Three waves of questionnaire surveys are planned for the REFUGE-study (REFUGE-I, II, and III). Collection for REFUGE-I has already been completed as described above. REFUGE-II and III are scheduled to be carried out roughly one and two years after REFUGE-I, respectively. The questionnaire used will be very similar for all three waves of the study. Key variables are highlighted in Table 2 below.

Table 2. Summary of key measures used in the longitudinal, three-wave, questionnaire survey

	Measure used[1]	Comments
Symptoms of PTSD	Harvard Trauma Questionnaire, HTQ	The first 16 items on trauma symptoms in section IV will be used
Symptoms of anxiety and depression	Hopkins Symptom Checklist, HSCL-25	The first 10 of the total 25 items will be used to measure symptoms of anxiety and the last 15 to measure symptoms of depression
Quality of life	World Health Organization Quality of Life assessment, WHOQOL-BREF	The scale consists of 26 items and all will be included
Somatic pain	Questions adapted from the Tromsø Study	10 questions will be used, 5 concerning muscle/joint pain and 5 concerning more general somatic pain
Perceived general health	European Social Survey	2 items from the scale will be included
Sleep difficulties	The Bergen Insomnia Scale	The scale consists of 6 items and all will be included
Potentially traumatic experiences *before* the flight from Syria (pre-migratory PTEs)	The Refugee Trauma History Checklist, RTHC	The scale consists of 8 items and all will be included
Potentially traumatic experiences *during* the flight from Syria (peri-migratory PTEs)	The Refugee Trauma History Checklist, RTHC	The scale consists of 8 items and all will be included
Post-migration stressful experiences	Post-migration stress scale	The scale consists of 24 items and all will be included
Social support	ENRICHD Social Support Inventory	The first 6 items of the scale will be included

[1] Further information on the measures used can be found in the ClinicalTrial.gov database where the study is registered (NCT03742128)

Other important measures in the questionnaire include an item regarding the re-experiencing of traumatic events or intrusive memories, which asks whether the participant experiences this, how often, and how distressing it is. Another item asks about the daily effects of chronic physical illness, disability, infirmity or mental health problem(s). Lastly, as an addition to the social support scale (ESSI), three items have been included to assess how easily the

respondent can get help from neighbours, how many people the participant can count on when serious problems occur, and how much concern people show in what the respondent is doing.

Background and sociodemographic variables

Important background and demographic variables include: gender, age, marital status, number of children, refugee status upon arrival (i.e. asylum seeker, quota refugee, family reunion, or other), whether the participant fled Syria alone or with a partner, family and/or friends, whether other family members had already settled in Norway prior to refugee's arrival in the country, time elapsed between when a participant fled Syria and arrived in Norway, and time in Norway prior to participating in the study. Tables 3 and 4 provide descriptive statistics on participants on the aforementioned variables from the first wave of data collection. The number of participants with missing values across variables can be interpreted from the table (applies for all tables). Additional sociodemographic data collected include: smoking; alcohol and drug use; employment status (*Do you currently hold paid employment in Norway? Yes/No)*; job satisfaction; self-reported competence in English and Norwegian language; and years of education completed (*How many years of schooling do you have? No education/1-5 years/6-9 years/10-12 years/More than 12 years)*. Further details on the scales used, their psychometric properties and how variables will be handled in analyses can be found in the ClinicalTrials.gov database.

Integration

Previous research has highlighted that active participation in social contexts promotes mental health, quality of life and beneficial health behaviours[16–18]. The REFUGE-study approaches integration in agreement with the primary domains suggested by Ager and Strang[19], which are: employment and labour market, school and education attainments, housing, and health and health care. Furthermore, and in line with suggestions by Castles[20] and Niemi et al[21], we consider civic and social participation/social exclusion to be central indicators of refugees' access to and active involvement in important spheres of the host societies, and these markers thus indicate a central component of social capital[22].

Table 3. Descriptive statistics on participating refugees from Syria

	Participants, *N* = 902		Participants willing to take part in longitudinal questionnaire survey, *N* = 665	
	n	(%)	*n*	(%)
Number of children				
I do not have children	271	(31.6)	213	(33.5)
1	63	(7.4)	44	(6.9)
2	125	(14.6)	86	(13.5)
3	139	(16.2)	103	(16.2)
4	101	(11.8)	78	(12.3)
5	77	(9.0)	53	(8.3)
6 or more	81	(9.5)	59	(9.3)
Total	857	(100.0)	636	(100.0)
Education[3]				
9 years or less	394	(44.7)	281	(43.0)
10-12 years	158	(17.9)	116	(17.8)
More than 12 years	330	(37.4)	256	(39.2)
Total	882	(100.0)	653	(100.0)
Refugee status upon arrival				
Asylum seeker	454	(52.5)	325	(51.0)
Quota refugee	273	(31.6)	209	(32.8)
Family reunion	133	(15.4)	100	(15.7)
Other	4	(0.5)	3	(0.5)
Total	864	(100.0)	637	(100.0)
Arrived in Norway...				
…alone	247	(28.1)	182	(28.0)
…with friends, but no family	56	(6.4)	43	(6.6)
…with family	576	(65.5)	425	(65.4)
Total	879	(100.0)	650	(100.0)
Family member previously settled in Norway				
No	594	(68.3)	440	(68.4)
Yes	276	(31.7)	203	(31.6)
Total	870	(100.0)	643	(100.0)
Length of flight[1]				
Less than 3 months	165	(33.7)	124	(33.9)
3 to 12 months	61	(12.4)	42	(11.5)
1 to 2 years	59	(12.0)	43	(11.7)
2 to 3 years	77	(15.7)	56	(15.3)
More than 3 years	128	(26.1)	101	(27.6)
Total	490	(100.0)	366	(100.0)
Residency time in Norway[2]				
Less than 2 years	104	(16.8)	83	(17.9)
Between 2 and 3 years	151	(24.4)	120	(25.9)
Between 3 and 4 years	289	(46.7)	209	(45.1)
More than 4 years	75	(12.1)	51	(11.0)
Total	619	(100.0)	463	(100.0)

[1] Estimated through the number of days elapsed between a refugee reportedly left Syria and arrived in Norway
[2] Estimated through the number of days elapsed between a refugee reportedly arrived in Norway and the date he/she returned the questionnaire

Table 4. Potentially traumatic experiences prior to and during the flight from Syria among participants

		Participants *N* = 902[1]		Participants willing to take part in longitudinal survey *N* = 665[1]	
		n	(%)	*n*	(%)
***Before* you left your home, have you personally faced any of the following situations or events:**					
War at close quarters	No	41	(4.7)	31	(4.8)
	Yes	840	(95.3)	618	(95.2)
Forced separation from family or close friends	No	324	(40.3)	235	(39.8)
	Yes	480	(59.7)	355	(60.2)
Loss or disappearance of family member(s) or loved one(s)	No	287	(35.3)	213	(35.5)
	Yes	526	(64.7)	387	(64.5)
Physical violence or assault	No	554	(70.5)	400	(69.3)
	Yes	232	(29.5)	177	(30.7)
Witnessing physical violence or assault	No	304	(36.9)	203	(33.5)
	Yes	520	(63.1)	403	(66.5)
Torture	No	567	(72.8)	410	(71.6)
	Yes	212	(27.2)	163	(28.4)
Sexual violence	No	710	(93.3)	518	(92.7)
	Yes	51	(6.7)	41	(7.3)
Other frightening situation(s) where you felt your life was in danger	No	103	(12.0)	74	(11.7)
	Yes	754	(88.0)	561	(88.3)
***After* you left your home, during your flight, have you personally faced any of the following situations or events:**					
War at close quarters	No	408	(49.3)	310	(50.7)
	Yes	420	(50.7)	302	(49.3)
Forced separation from family or close friends	No	412	(52.5)	298	(51.5)
	Yes	373	(47.5)	281	(48.5)
Loss or disappearance of family member(s) or loved one(s)	No	422	(53.8)	312	(53.6)
	Yes	362	(46.2)	270	(46.4)
Physical violence or assault	No	638	(83.6)	467	(83.5)
	Yes	125	(16.4)	92	(16.5)
Witnessing physical violence or assault	No	566	(72.6)	405	(70.7)
	Yes	214	(27.4)	168	(29.3)
Torture	No	657	(86.8)	481	(87.1)
	Yes	100	(13.2)	71	(12.9)
Sexual violence	No	722	(97.3)	529	(97.2)
	Yes	20	(2.7)	15	(2.8)
Other frightening situation(s) where you felt your life was in danger	No	350	(42.8)	258	(42.9)
	Yes	468	(57.2)	344	(57.1)

[1] Not all participants answered all items, therefore, the total number of answers for a given item may be less than 902 and 665 for the two groups, respectively.

Congruent with the domains of integration suggested by Ager and Strang, the study will use data from the Norwegian national registries in order to measure integration for consenting participants. Specifically, the study plans to obtain data from the National education database (NUBD) which contains data on educational participation and achievements; the Norwegian registries on employment and sick-leave which contain data on employment and doctor-certified sick-leave; the Norwegian Patient Registry (NPR) and the Norwegian Registry for Primary Health Care (NRPHC) which contain data on the utilization of the health care system; and, finally, the Norwegian Prescription Database (NorPD) which contains data about dispensed drugs. All of the registries contain individual-level data, and the study intends to merge a participant's longitudinal survey data with that participant's registry data at in order to investigate how mental health is associated with these measures of integration.

Integration will also be investigated through the questionnaire data. Social integration is explored through measures of post migratory stress (e.g. "Often felt excluded or isolated in the Norwegian society", "Often being unable to buy necessities"), social support (ESSI) and quality of life. Furthermore, the questions on how easily the participant can get help from neighbours; how many people the participant can count on when serious problems occur; and how much concern people show in what the participant is doing will also be used as measures of integration. In the coming data collection waves, a scale measuring social participation will also be included. This scale will be incorporated both in the quantitative part of the study and as a specific topic within the planned qualitative interviews and focus groups.

Analysis

The study's registration in the ClinicalTrials.gov database presents detailed analytic plans for the first phase of the REFUGE-study (REFUGE-I). Broad analytic questions to be investigated in the later phases of the REFUGE-study include: i) what are important risk and protective factors for mental ill health; ii) what are the mental health trajectories and which factors appear to impact these trajectories; iii) how is mental health associated with the measures of integration used in the present study and what are important mediators and modifiers in the relationship between mental health and integration.

Qualitative measures

In addition to the quantitative aspect of the REFUGE-study, qualitative analyses are also planned for future waves of the study, comprising interviews and focus group sessions.

Questions regarding participation and non-participation will be included in interview guides. Further themes for the interview and focus group guides are in development, and directions will be refined as further findings emerge from the existing quantitative dataset.

Patient and public involvement

The REFUGE-study was supported throughout the development process by members of the community. Focus groups were held in the early stages of development in order to tailor the questionnaire, and a user reference group was created in order to act as an advisory group, providing insight during the planning, development and implementation stages. Community members were also involved in the recruitment process, providing insight and advice on the dissemination of information about the study through social media.

Findings to date

The first wave of data collection in Norway has been completed. At the time of writing, no findings have been published.

Strengths and limitations

The REFUGE-study has several important strengths, both in terms of methodology, and in value of the resulting data. Firstly, the study population was randomly selected from a large source population consisting of all adult refugees from Syria residing in Norway who met the study's eligibility criteria, obtained from the Norwegian National Registry. In comparison, many of the previous studies on mental health in refugee populations rely on convenience sampling. Further, the use of a three-wave longitudinal survey design will allow for better exploration of cause-effect relationships between variables in the study, than purely cross-sectional data. In addition, research on the association between refugee mental health and integration is scarce. By linking longitudinal questionnaire data to registry data on education-, work- and health-related parameters, the study could make important contributions to the dearth of evidence on this topic. Also, combining self-report data with registry data from well-established national registries may reduce common method bias. Research on refugee mental health to date relies heavily on self-report data. A further strength of the study is that most of the key variables are measured using well-documented and validated scales. Review articles on refugee mental health frequently highlight the large degree of variance in terms of methods used and call for increased focus on methodological issues. Lastly, the close collaboration between the REFUGE-study group in Norway and its main collaborating

partner, the Red Cross University College in Sweden, will offer ample opportunities to compare Syrian refugee populations in two different countries, as both projects use similar measures and have agreed to collaborate on and combine datasets.

An important potential weakness of REFUGE-I is that less than 11 percent of the sampled population participated in the study. This could lead to selection bias problems. As can be seen from Table 1, participants are very similar to the source and sample population in terms of gender, though the proportion of young and unmarried refugees are notably smaller in the participating group. Table S2 in the supplementary material shows that the geographical distribution across Norway's 18 counties was very similar for participants and the sample population. In terms of residency status, participants had the same proportional breakdown as the sample population: 95% had temporary residency in Norway at the time of the survey and 5% had permanent residency (result not shown in tables). In order to further explore selection bias, we investigated whether there were any trends across demographic and background variables in terms of when the surveys were filled out and returned. Given that the survey was open for nine months, exploring the timing of participation may give some indication of different groups' willingness to participate, and, by extension, suggest which groups may be over- and underrepresented among participants. While the most common reason for non-participation was unwillingness, a potentially significant contributing factor to the low participation rate may be the presence of low literacy rates within the sampled population. As shown in Figure 1, 49 participants stated an inability to read Arabic to explain non-participation, and it is conceivable that this was the case for a number of sampled individuals who failed to return the survey. Regrettably, current ethical laws in Norway do not allow for an online-based questionnaire where Arabic voice-over could be utilized. Therefore, potential participants with low reading and writing proficiency regrettably were effectively excluded.

Table S3 in the supplementary material shows the distribution of demographic variables across 4 different time-periods of participation (i.e. the 9-month period the survey was open was divided into 4 shorter periods), and Table S4 shows the distribution across background characteristics related to refugee status and history. Differences in distributions across time-periods were tested with chi-square test of equal proportion. As can be seen from the tables, there was weak or no evidence that the timing of participation was related to demographic and/or background variables with three exceptions. First, there was very clear evidence that residency time in Norway was negatively associated with early participation -

i.e. the longer a refugee's residency time in Norway, the less likely (s)he was to participate in the first time-periods following study launch ($p < 0.001$), relatively speaking. There was also very strong statistical evidence ($p < 0.001$) that pre-migratory stress was associated with the timing of participation, though the underlying trend was not easily interpretable. Refugees with the highest number of potentially traumatic pre-flight experiences (PTEs) were more likely to participate in the early periods after study launch (relatively speaking). This was not true, however, for the refugee group with the second to most PTEs. Lastly, there was moderate evidence that refugee status upon arrival was association with the timing of participation ($p = 0.01$), though no clear underlying pattern was evident.

Another limitation of the present study is the survey design used to attain prevalences of depression, anxiety and PTSD symptoms. Short-form questionnaires, while efficient, do not capture all aspects of the measured constructs. Additionally, recent studies have suggested that when self-report measures are used, resulting prevalences tend to be higher than when using diagnostic interviews[23,24]. However, the questionnaires used in the current study to measure PTSD, anxiety and depression have been validated for use within the studied population and their use allows for many more participants to be reached, improving the generalizability of the findings.

Perhaps the most significant learning opportunity provided by the present study thus far has been the challenging recruitment process. Although extensive recruitment efforts were employed, the participation rate for REFUGE-I was just above 10%. As noted previously, methods to boost recruitment involved the utilisation of contacts within the community, dedicated Facebook and web pages in Arabic, and Q&A sessions held at Adult Education centres in Norway's major cities, as well as the dissemination of information about the project online through purpose-built, animated videos and newsletters. Researchers aiming to gather data from similar populations would do well to ensure that sufficient time and resources are dedicated to the recruitment phase of the study.

Future plans

The REFUGE-cohort study will conduct a second wave of data collection in 2020. A third wave of data collection is planned in 2021, pending funding. Furthermore, we plan to link questionnaire data to Norwegian registry data after all three waves of data collection have been completed. Registry data will be obtained for time-periods both prior to and after the three-wave survey. Primary and secondary objectives with detailed plans for analyses for

studies involving registry data will be registered at ClinicalTrials.gov prior to obtaining the registry data, so that true hypothesis-testing studies from the REFUGE-cohort are distinguishable from more exploratory and data-driven studies. Finally, pending ethics approval, we will begin the process of merging the Norwegian REFUGE-cohort with existing datasets in Sweden, creating the REFUGE-database.

Parallel to completing the survey data collection, data-merging and registry data obtainment, we aim to publish papers in accordance with our pre-registered publication plan at ClinicalTrials.gov.

COLLABORATION

We welcome potential collaboration with other research groups. Interested researchers should contact the REFUGE research group for collaboration and knowledge-sharing. Locally collected data can then be added to the REFUGE-database. Reference estimates (e.g. prevalence, incidence and associations) can then be continuously updated and made available to researchers abiding by the EU's GDPR laws and regulations. In addition, the REFUGE-database will also include data obtained through Scandinavian social and health-registries.

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Competing Interests: None declared.

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Data availability: Deidentified participant data will be made available for reuse upon reasonable request pending ethics approval, compliance with the General Data Protection Regulation (GDPR), and discretion of the research group with regard to the prospective research project proposal. Requests should be sent to refuge@nkvts.no. Additional information regarding the scales used, statistical analysis plans and future data collection is available through ClinicalTrials.gov (NCT03742128).

Figure legend:

Figure 1: Flowchart of participants through the study.

[1] Refugees were either resettlement/quota refugees; asylum seekers who were granted asylum in Norway; or individuals coming through the program *Family immigration with a person*

who has protection (asylum) in Norway. The source population was identified through the Norwegian National Registry (NNR)

[2] Information was obtained when non-responders were contacted during the telephone reminder

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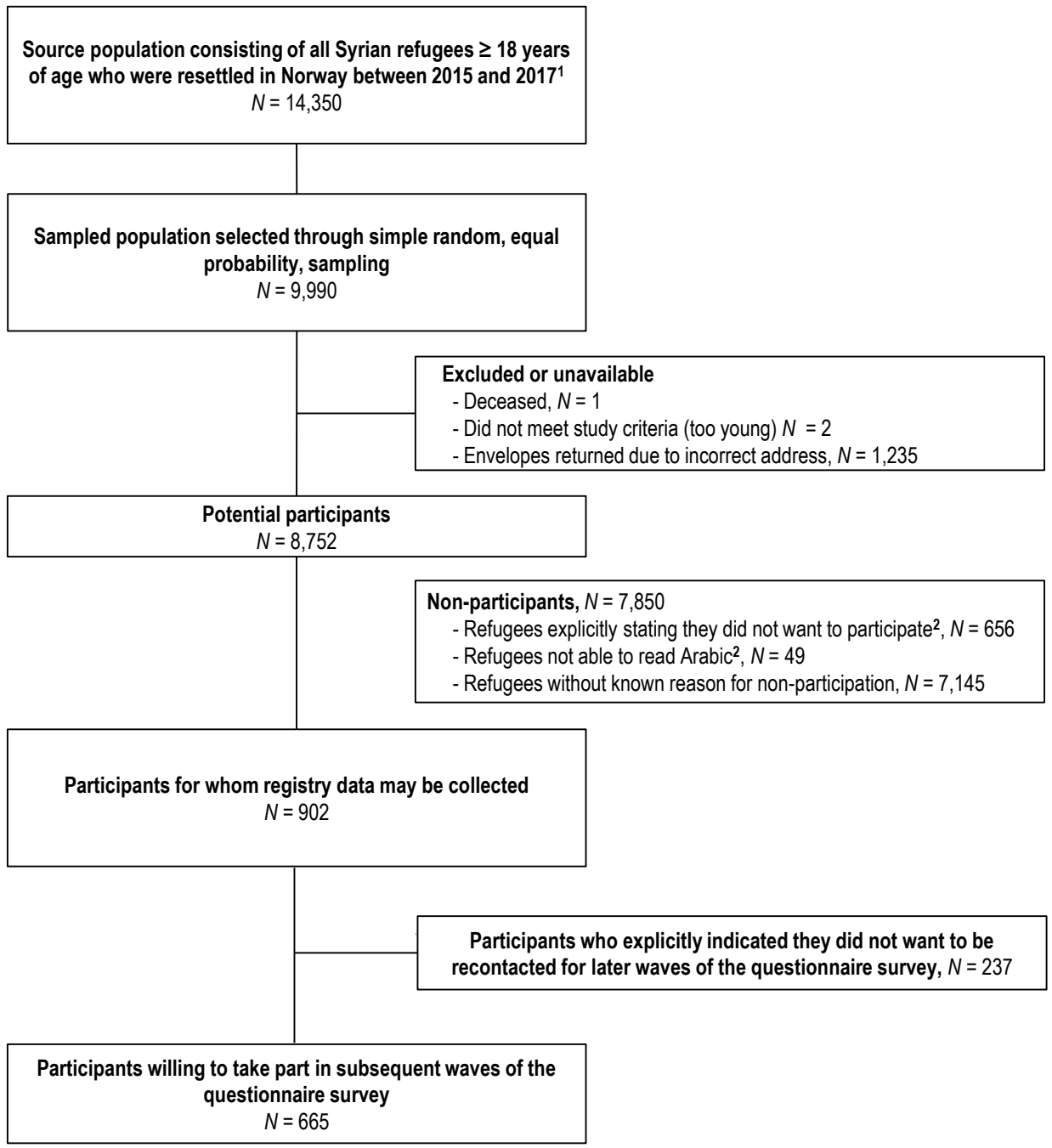
Source population consisting of all Syrian refugees ≥ 18 years of age who were resettled in Norway between 2015 and 2017[1]
N = 14,350
Sampled population selected through simple random, equal probability, sampling
N = 9,990
Excluded or unavailable
- Deceased, N = 1
- Did not meet study criteria (too young) N = 2
- Envelopes returned due to incorrect address, N = 1,235
Potential participants
N = 8,752
Non-participants, N = 7,850
- Refugees explicitly stating they did not want to participate[2], N = 656
- Refugees not able to read Arabic[2], N = 49
- Refugees without known reason for non-participation, N = 7,145
Participants for whom registry data may be collected
N = 902
Participants who explicitly indicated they did not want to be recontacted for later waves of the questionnaire survey, N = 237
Participants willing to take part in subsequent waves of the questionnaire survey
N = 665

Table S1. Responses given by initial non-responders during telephone reminder sessions (N = 2,087)

	N	(%)
Answers given by refugees		
Would like to participate and does not need a new questionnaire	403	(19.1)
Would like to participate and needs a new questionnaire	856	(40.8)
Does not want to participate	656	(30.8)
Moved and wants a new questionnaire	69	(3.3)
Moved and does not want a new questionnaire	29	(1.4)
Wrong number/person	25	(1.2)
Does not understand Arabic	49	(2.4)
Total	2,087	(100.0)

Table S2. Geographical distribution across Norway's 18 counties for participants and sample population of refugees from Syria

	Sample population N = 9,990		Participants N = 902	
	n	(%)	n	(%)
Akershus	703	(7.0)	52	(5.7)
Aust-Agder	347	(3.5)	30	(3.3)
Buskerud	470	(4.7)	39	(4.3)
Finnmark	254	(2.5)	23	(2.6)
Hedmark	311	(3.1)	30	(3.3)
Hordaland	1,009	(10.1)	88	(9.8)
Møre og Romsdal	486	(4.9)	51	(5.7)
Nordland	670	(6.7)	65	(7.2)
Oppland	381	(3.8)	37	(4.1)
Oslo	773	(7.7)	70	(7.9)
Rogaland	831	(8.3)	63	(7.0)
Sogn og Fjordane	380	(3.8)	34	(3.8)
Telemark	398	(4.0)	40	(4.4)
Troms	449	(4.5)	51	(5.7)
Trøndelag	1,049	(10.5)	96	(10.5)
Vest-Agder	520	(5.2)	50	(5.5)
Vestfold	475	(4.8)	44	(4.9)
Østfold	484	(4.9)	39	(4.3)
Total	9,990	(100.0)	902	(100.0)

Table S3. Demographic characteristics of participating refugees from Syria according to when they returned the questionnaire

	4th quarter 2018		1st quarter 2019		2nd quarter 2019		3rd quarter 2019		Total		Chi-square
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	
Gender											0.08
Male	278	(64.2)	66	(69.5)	157	(68.0)	77	(55.8)	578	(64.4)	
Female	155	(35.8)	29	(30.5)	74	(32.0)	61	(44.2)	319	(35.6)	
Total	433	(100.0)	95	(100.0)	231	(100.0)	138	(100.0)	897	(100.0)	
Age groups											0.36
18-29	87	(20.1)	28	(29.5)	50	(21.6)	31	(22.5)	196	(21.9)	
30-39	142	(32.8)	28	(29.5)	88	(38.1)	50	(36.2)	308	(34.3)	
40-49	122	(28.2)	19	(20.0)	52	(22.5)	36	(26.1)	229	(25.5)	
50-64	72	(16.6)	19	(20.0)	37	(16.1)	16	(11.6)	144	(15.6)	
>64	10	(2.3)	1	(1.0)	4	(1.7)	5	(3.6)	20	(2.7)	
Total	433	(100.0)	95	(100.0)	231	(100.0)	138	(100.0)	897	(100.0)	
Civil status											0.10
Unmarried	121	(27.9)	31	(32.6)	60	(26.0)	22	(15.9)	234	(26.1)	
Married	276	(63.7)	58	(61.1)	154	(66.7)	104	(75.4)	592	(66.0)	
Other[1]	36	(8.3)	6	(6.3)	17	(7.4)	12	(8.7)	71	(7.9)	
Total	433	(100.0)	95	(100.0)	231	(100.0)	138	(100.0)	897	(100.0)	
Education											0.53
9 years or less	187	(44.4)	38	(42.2)	111	(48.7)	53	(38.4)	389	(44.4)	
10-12 years	74	(17.6)	18	(20.0)	35	(15.4)	31	(22.5)	158	(18.0)	
More than 12 years	160	(38.0)	34	(37.8)	82	(36.0)	54	(39.1)	330	(37.6)	
Total	421	(100.0)	90	(100.0)	228	(100.0)	138	(100.0)	877	(100.0)	

[1] Includes: divorced, widow(er), separated

Table S4. Refugee and migratory characteristics of participating refugees from Syria according to when they returned the questionnaire

	4th quarter 2018		1st quarter 2019		2nd quarter 2019		3rd quarter 2019		Total		Chi-square
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	
Ref. status upon arrival											0.01
Asylum seeker	208	(50.5)	54	(61.4)	122	(54.7)	66	(48.5)	450	(52.4)	
Quota refugee	147	(35.7)	20	(22.7)	70	(31.4)	35	(25.7)	272	(31.7)	
Family reunion	55	(13.3)	14	(15.9)	31	(13.9)	33	(24.3)	133	(15.5)	
Other	2	(0.5)	0	(0.0)	0	(0.0)	2	(1.5)	4	(0.5)	
Total	412	(100.0)	88	(100.0)	223	(100.0)	136	(100.0)	859	(100.0)	
Arrived in Norway...											0.47
...alone	121	(28.8)	30	(32.6)	64	(28.1)	31	(23.0)	246	(28.1)	
...with friends only	31	(7.4)	7	(7.6)	11	(4.8)	7	(5.2)	56	(6.4)	
...with family	268	(63.8)	55	(59.8)	153	(67.1)	97	(71.9)	573	(65.5)	
Total	420	(100.0)	92	(100.0)	228	(100.0)	135	(100.0)	875	(100.0)	
Length of flight											0.87
Less than 3 months	110	(35.7)	28	(38.4)	65	(39.9)	39	(37.5)	242	(37.6)	
3 to 12 months	33	(10.7)	6	(8.2)	20	(12.3)	14	(17.5)	73	(11.3)	
1 to 2 years	40	(13.0)	9	(12.3)	20	(12.3)	10	(7.5)	79	(12.3)	
2 to 3 years	40	(13.0)	14	(19.2)	24	(14.7)	15	(17.5)	93	(14.4)	
More than 3 years	85	(27.6)	16	(21.9)	34	(20.8)	22	(20.0)	157	(24.4)	
Total	308	(100.0)	73	(100.0)	163	(100.0)	100	(100.0)	644	(100.0)	
Residency time in Norway											<0.001
Less than 2 years	81	(22.0)	14	(17.3)	22	(11.3)	9	(8.2)	126	(16.7)	
2-3 years	82	(22.2)	16	(19.8)	39	(20.0)	27	(24.6)	164	(21.7)	
3-4 years	184	(49.8)	44	(54.3)	106	(54.4)	51	(46.3)	385	(46.4)	
More than 4 years	22	(6.0)	7	(8.6)	28	(14.3)	23	(20.9)	80	(10.6)	
Total	369	(100.0)	81	(100.0)	195	(100.0)	110	(100.0)	755	(100.0)	
PTEs before flight[1]											<0.001
0-1	34	(7.9)	10	(10.6)	34	(14.8)	15	(11.3)	93	(10.5)	
2-3	101	(23.4)	25	(26.6)	86	(37.4)	29	(21.8)	241	(27.1)	
4-5	185	(42.9)	34	(36.2)	75	(32.6)	64	(48.1)	358	(40.3)	
>5	111	(25.8)	25	(26.6)	35	(15.2)	25	(18.8)	196	(22.1)	
Total	431	(100.0)	94	(100.0)	230	(100.0)	133	(100.0)	888	(100.0)	
PTEs during flight[1]											0.46
0-1	154	(36.8)	31	(34.1)	96	(42.7)	54	(41.9)	335	(38.8)	
2-3	143	(34.2)	32	(35.1)	71	(31.6)	33	(25.6)	279	(32.3)	
4-5	89	(21.3)	19	(20.9)	48	(21.3)	32	(24.8)	188	(21.8)	
>5	32	(7.7)	9	(9.9)	10	(4.4)	10	(7.7)	61	(7.1)	
Total	418	(100.0)	91	(100.0)	225	(100.0)	129	(100.0)	863	(100.0)	

[1] All individuals with at least one answered item on the PTE-scale were given a sum-score for total PTEs before/during flight