The impact of detention on the health of asylum seekers: a protocol for a systematic review

PROTOCOL

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1 Background

1.1 DESCRIPTION OF THE CONDITION

The last decades of the twentieth century were accompanied by an upsurge in the number of persons fleeing persecution and regional wars. The office of the United Nations High Commissioner for Refugees (UNHCR) has reported that 479,300 asylum applications were received by 44 industrialized countries\(^1\) in 2012 (UNHCR, 2012). Eurostat provides statistics on the gender and age distribution of asylum seekers in EU, the most recent data being from January 2013 where males account for 66 per cent; children under 18 years, 26 per cent; those aged 18-34 years, 53 per cent; and those 35 years and older, 21 per cent\(^2\).

Western countries have applied increasingly stringent measures to discourage those seeking asylum from entering their countries (UNHCR, 2000; Human Rights Watch, 2001). There are various strategies aimed at deterring the influx of asylum seekers. These include confinement in detention centres, enforced dispersal within the community, more stringent refugee determination procedures, and temporary forms of asylum. In several countries, asylum seekers living in the community face restricted access to work, education, housing, welfare, and in some situations, to basic health care services (Silove, Steel & Watters, 2000).

The most controversial of the measures to discourage people from seeking asylum is the decision by some western countries to confine asylum seekers in detention facilities (Loff, 2002; Summerfield, Gorst-Unsworth, Bracken, Tonge, Forrest & Hinshelwood, 1991). Many countries detain asylum seekers; however, Australia has been unique in establishing a policy of mandatory, indefinite detention. From 1992 to 2005, Australia implemented a policy of mandatory detention of all asylum seekers arriving by boat or without valid travel documents. This policy has been

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\(^1\) These are: 27 Member States of the European Union, Albania, Bosnia and Herzegovina, Croatia, Iceland, Liechtenstein, Montenegro, Norway, Serbia, Switzerland, The former Yugoslav Republic of Macedonia, and Turkey, as well as Australia, Canada, Japan, New Zealand, the Republic of Korea and the United States of America.

\(^2\) See http://appsso.eurostat.ec.europa.eu/nui/submitViewTableAction.do
much criticised (Phillips & Spinks, 2011) and in November 2011, Australia changed its policy aimed at limiting the time asylum seekers are held in detention (Cleveland, Rousseau & Kronick, 2012). Recently the Australian government announced a policy in which any asylum seeker arriving by boat without a visa will be refused settlement in Australia, instead being settled in Papua New Guinea (PNG) if they are found to be legitimate refugees (Regional resettlement arrangement between Australia and Papua New Guinea, 2013). The UNHCR has expressed concern with the new policy, especially the lack of national capacity and expertise in processing, and poor physical conditions within open-ended, mandatory and arbitrary detention settings (UNHCR, 2013).

Since the events of 9/11, other countries such as the USA and the UK (Welch & Schuster, 2005; American Civil Liberties Union (ACLU), 2007) have expanded immigration detention facilities and the use of detention. A similar trend appears to have emerged in Canada (Nyers, 2003; Lacroix, 2006). In December 2012 Canada implemented changes to the refugee determination system inter alia implying that asylum seekers aged 16 or older and designated as part of an “irregular arrival” will be detained (Cleveland, Rousseau & Kronick, 2012; Canadian Council for Refugees, 2012). Furthermore, in a number of continental European countries, the use of detention has significantly increased and is often used as a first resort rather than last resort (Council of Europe, 2010).

Asylum seekers are detained at different stages of the asylum process. Detention is also used by most European countries to facilitate deportations (Schuster, 2004). Hence, recently arrived asylum seekers as well as asylum seekers whose appeals have not yet been heard are held in detention. In many European countries, deportation orders are issued concurrently with the initial rejection of the asylum claim (Schuster, 2004; Hughes & Liebaut, 1998).

Little is known about why people are detained and there are no official statistics on how many asylum seekers are detained or for how long (Hughes & Liebaut, 1998; The Information Centre about Asylum and Refugees (ICAR), 2007).

A few countries do provide some information regarding number and duration of detention of asylum seekers, however. In Australia, immigration detention statistics are provided by the Department of Immigration and Citizenship. Here, the statistic is given as a monthly snapshot on a particular date as opposed to a general annual total. As of 31 May 2013 there were 8,521 persons in immigration detention.
facilities\(^3\) of which 79 per cent were males and 18 per cent were children (less than 18 years of age). The average duration of detention is likewise given only as a snapshot, and calculated as the average length of time (so far) for persons held in detention at a particular date. Thus no statistics are published of the overall periods spent in detention by each detainee. The snapshot average length has decreased from 277 days in November\(^4\) 2011 to 74 days as of 31 May 2013. In the UK, the Home Office provides statistics in quarterly snapshots. As of 30 September 2012 there were 3,091 immigrants in detention (excluding persons detained in police cells and in prison establishments\(^5\)); of these, 56 per cent had claimed asylum, 89 per cent were males and none were children. The average duration is not provided and cannot be calculated but the median is approximately two weeks. The length of stay is not provided separately for immigrants who had sought asylum.

Little is known about why people are detained. There is no accessible legal framework governing the use of detention under either international human rights law or refugee law. According to the Council of Europe (2010), the national laws and regulations of many countries are insufficient and leave too much at the discretion of immigration officials. Detention policies are non-transparent, which may imply a certain degree of arbitrariness in the decision process (Council of Europe, 2010).

Since 1999, UNHCR Guidelines (UNHCR 1999c) have suggested considering the following as possible alternatives to detention monitoring requirements: provision of a guarantor/surety, release on bail, and open centres (JRS Europe policy). There are many ways in which these alternatives to detention are implemented in practice. JRS Europe\(^6\) emphasises that the type of alternative to detention that a government uses must fit the country's particular context, and especially the needs of the migrants who are participating in that alternative (JRS Europe, 2012)

That the decision to detain is often arbitrary is also stated by the UNHCR: “In many States the decision to detain is taken on the basis of sometimes very wide discretionary powers, often not prescribed by law. Moreover, even when the grounds upon which such orders are made are established in law, these are far too frequently applied in an arbitrary manner,” (UNHCR, 1999a, p. 3).

\(^3\) Including alternative places of detention.  
\(^4\) No exact date is reported.  
\(^5\) According to ICAR (2007) there were approximately 500 immigration detainees held in prisons whose whereabouts are often unknown and unrecorded in Home Office statistics in 2006  
\(^6\) Jesuit Refugee Service Europe
Although UNHCR guidelines on the detention of asylum seekers include the right to an automatic independent judicial review of all decisions to detain followed by periodic reviews of the necessity to continue to detain, several member states do not comply with UNHCR’s guidelines on the detention of asylum seekers (Human Rights Watch, 2001; UNCHR, 2000).

There is, however, growing evidence that the detention of asylum seekers is associated with substantial mental health problems (Silove, Steel & Mollica, 2001; Fazel & Silove, 2006; Physicians for Human Rights and the Bellevue/NYU Program for Survivors of Torture, 2003). The Bellevue/NYU Program for Survivors of Torture (Bellevue/NYU) and Physicians for Human Rights study reports that significant symptoms of depression were present in 86% of the detained asylum seekers; anxiety was present in 77% and PTSD in 50%. Hence, the mental health of asylum seekers was extremely poor and worsened the longer these individuals were in detention.

One important question arises from this: Is there any evidence of a causal effect of detention on the mental problems of asylum seekers? Research using appropriate controls can provide some relevant evidence on whether detention might cause adverse outcomes on asylum seekers: Considering the particular population under investigation in this review, it is vital that an appropriate comparison group is used to establish causality.

Another concern is that diagnostic difficulties can arise in a multi-cultural context, particular when applying some Western mental health diagnoses to other cultures. The ways of expressing distress and views on the causes of that distress may differ markedly from that of the dominant ‘Western’ culture. For example, depression may be seen as the result of ‘thinking too much’ or of witchcraft (Patel, Simunyu & Gwanzura, 1995; Patel, 1995). Some ethnic groups do not have certain Western diagnostic concepts, such as alcoholism, in their vocabulary, and the stigma attached to mental illness in some cultures may even be greater than in Western society (Paton & Jenkins, 2002). Furthermore, although similar symptoms may exist in different cultures, they do not necessarily have the same value or meaning and there is variation in what is understood to constitute “normal” emotional expression. For example, in some cultures dreams of the dead are perceived as positive and comforting (Zur, 1996). Kirmayer (1996) discusses differences between cultures in how conscious and non-conscious ways of dealing with distress are promoted, and notes that intrusion and avoidance symptoms vary in their “normality” across cultures.
Asylum seekers often come from countries in conflict and many asylum seekers have experienced pre-migration adversities that may have affected their health (Silove et al., 2000; Robjant, Hassan & Katona, 2009). High rates of pre-migration trauma, and therefore of trauma-related mental health problems, have been reported (Sinnerbrink, Silove, Field, Steel & Manicavasagar, 1997). However, research into post-migration adversities suggests that aspects of the asylum-seeking process may compound the stressors suffered by an already traumatized group (Sinnerbrink et al., 1997). Similarly, Silove et al. (1997) conclude: “Our findings raise the possibility that current procedures for dealing with asylum-seekers may contribute to high levels of stress and psychiatric symptoms in those who have been previously traumatised,” (Silove et al., 1997, p. 351). Seven common post-migration adversities are identified (termed the ‘seven Ds’): Discrimination, Detention, Dispersal, Destitution, Denial of the right to work, Denial of healthcare, and Delayed decisions on asylum applications (see McColl, McKenzie & Bhui, 2008).

Hence, as detention is not the only post-migration stressor and considering the fact that the population under investigation in this review most likely has high rates of pre-migration trauma; we believe it is vital that an appropriate comparison group is used to establish causality.

The main objective of this review is to assess what is known about the causal effects of detention on asylum seekers’ mental health. The aim is to uncover and synthesize relevant studies that measure the causal effects on mental health of detaining asylum seekers. Although the primary focus is on mental health, all outcomes reported in studies comparing detained asylum seekers with a comparable non-detained group will be examined.

We are aware that tight causal conclusions can probably not be drawn from the studies we expect to find, as we do not expect to find any studies based on trials. However, a distinction can be drawn between studies that simply assess the association between the detention of asylum seekers and mental health outcomes, and studies that control for important confounding factors. Studies that control for important confounding factors provide some evidence for considering possible causal effects. While conclusions about causal effects must be very tentative, it is important to extract and summarize the best evidence available.
1.2 DESCRIPTION OF THE INTERVENTION

In this review, the detention of asylum seekers will be regarded as a social intervention – with possible adverse consequences for the asylum seekers. We define detention as the deprivation of liberty for asylum seekers in the host country. Those detained may be held in various facilities (immigration holding centres, remote camps or provincial jails) which may be run by public authorities or by private companies. In most countries, the detention of asylum seekers is an administrative procedure that is undertaken to verify the identity of individuals, process asylum claims, and/or ensure that a deportation order is carried out (The Global Detention Project, www.globaldetentionproject.org). It is important to note that one of the key concerns vis-a-vis this form of detention is precisely its administrative nature. Domestic legal systems are rarely detailed regarding these detention situations, which can result in detainees facing legal uncertainty (including lack of access to the outside world, e.g. to legal counsel), inadequate or no possibilities of challenging detention through the courts, and lack of limitations on the duration of detention. Living conditions differ, but in many countries detention centres are operated as if they were prisons, with barred windows, high-wire perimeter fencing, and with limited access to information, health care services and psychological support (The Global Detention Project and Amaral, 2010).

1.3 HOW THE INTERVENTION MIGHT WORK

Asylum seekers who are detained in the host country experience a set of stressors, reflecting the detention process itself and the detention centre environment, which may adversely affect their mental health status. These include loss of liberty, uncertainty regarding return to their country of origin, uncertain duration of detention, social isolation, separation from families, abuse from staff, riots, forceful removal, hunger strikes, and self-harm (Fazel & Silove, 2006; Pourgourides, Sashidharan & Bracken, 1996; Keller et al., 2003).

How the mental health status of detained asylum seekers after release relates to the nature of their experience of detention has rarely been subjected to detailed examination and only a few such studies exist.

In the Bellevue/NYU Program for Survivors of Torture (Bellevue/NYU) and Physicians for Human Rights study, it is reported that confinement and the loss of liberty profoundly disturbed asylum seekers and triggered feelings of isolation,
powerlessness and disturbing memories of persecution that asylum seekers had suffered in their countries of origin. The study by Amaral (2010) shows that detention and the negative factors associated with it have a significant deteriorative effect on asylum seekers’ self-perception, with minors and long-term detainees appearing to suffer the most.

Further research was undertaken in the Coffrey, Kaplan, Sampson & Tucci (2010) study, in order to examine the experience of detention from the perspective of the detained asylum seekers, and to identify the consequences of these experiences for their life after release. Detention was experienced as a dehumanizing environment characterized by confinement, deprivation, injustice, inhumanity, isolation, fractured relationships, and mounting hopelessness and demoralization.

The probable mechanisms by which the harmful effects of detention were transmitted appear to include the following: Changes in self-perception, changes in relationships in accordance with how the detainee was perceived and treated by others and by “the system,” and alteration of core values. These mechanisms are recognized in psychological literature, especially in the trauma field, as ways in which negative psychological effects are maintained following experiences which threaten the self (Herman, 1997; Lifton, 1993; Abernathy, 2008; Campbell, Brunell & Foster, 2004; Janoff-Bulman, 1992).

Certain types of people are regarded as being vulnerable, i.e. they may be especially susceptible to harm in detention. Women, children, unaccompanied minors and persons with a mental or physical disability are widely acknowledged to be vulnerable (Amaral, 2010). Amaral defines vulnerability as a “loss of control over oneself to someone, or something, with more power, thus making oneself susceptible to some type of harm,” (Amaral, 2010, p. 94). He concludes that the lack of information regarding asylum procedures, duration and reasons for detention and expected release is a critical indicator of detainees’ ability to cope with their time in detention. According to Amaral (2010), younger detainees aged 10 to 24 are reported to possess less information compared to older detainees. Women in general, but especially women aged 18-24, are reported to possess less information than men do. Thus younger detainees, and especially younger women, seem to particularly suffer from detention.

The UNHCR definition of vulnerable groups in addition to the ones mentioned above includes torture or trauma victims (UNHCR, 1999b).
This points towards another important aspect of the probable mechanisms by which detention may adversely affect detainees. Research suggests that asylum seekers worldwide report high rates of pre-migration trauma and adversities (e.g. war, imprisonment, genocide, physical and sexual violence, witnessing violence to others, traumatic bereavement, starvation and homelessness), (Sinnerbrink, Silove, Field, Steel & Manicavasagar, 1997; McColl et al, 2008), and therefore of trauma-related mental health problems. The process of seeking asylum in Western countries places additional demands on this group. Post-migratory stressors, in particular detention, seem to negatively affect this population, who are already vulnerable to mental health difficulties as a result of their previous exposure to traumatic events. Even though captivity is stressful in any context and in particular when it occurs over an indeterminate period, it may be even more stressful to people who have had previously traumatic experiences (Pourgourides, 1997; Paton & Jenkins, 2002). The experience of detention may reactivate and exacerbate previous trauma. For example, the Medical Foundation for the Care of Victims of Torture (1994) reports that the indeterminate detention experienced by asylum seekers who have previously been imprisoned and tortured may prolong the psychological ‘demolition’ of the person and cause high levels of stress, despair and anxiety.

1.4 WHY IT IS IMPORTANT TO DO THIS REVIEW

Given the well-documented vulnerability of asylum seekers as a result of traumatic experiences prior to arrival, a number of clinicians have expressed concern that detention increases mental health difficulties in adult and child asylum seekers, and have called for an end to such practices (Salinsky, 1997; Koopowitz & Abhary, 2004; Fazel & Stein, 2004). This is clearly in conflict with government policies aimed at reducing the numbers of asylum seekers (Silove et al., 2000).

An obvious question arises: Is it worth conducting a systematic review when the likelihood is that few trial based studies are expected to be found? We believe so, as a systematic review may uncover high quality studies that may not be found using less thorough search methods. Secondly, if a systematic review demonstrates that high quality studies are lacking, this could encourage a new generation of primary research. Hence, even though we do not expect to find any trial based studies and very few studies of the detention of asylum seekers based on control group comparison, we still believe it is worth conducting the proposed review in order to gather and highlight the best available knowledge.
2 Objective of the review

The main objective of this review is to assess evidence about the effects of detention on the mental and physical health and social functioning of asylum seekers.
3 Methods

3.1 CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

3.1.1 Types of studies

Due to ethical considerations, it is hard to imagine that a researcher would control the allocation of asylum seekers to detention and non-detention conditions. We therefore anticipate that relatively few controlled trials on the effects of detention on the mental and physical health and social functioning of asylum seekers will be found. However, in the unlikely event that a controlled trial is found, it will of course be included in the review. In order to summarize what is known about the possible causal effects of detention, we will include all study designs that use a well-defined control group as, for example, asylum seekers in the same country who are not detained. Non-randomised studies, where the use of detention has occurred in the course of usual decisions outside the researcher’s control, must demonstrate pre-treatment group equivalence via matching, statistical controls, or evidence of equivalence on key risk variables and participant characteristics. These factors are outlined in section 3.4.3 under the subheading of Confounding, and the methodological appropriateness of the included studies will be assessed according to the risk of bias model outlined in section 3.4.3.

The study designs we will include in the review are:

A. Controlled trials (where all parts of the study are prospective, such as identification of participants, assessment of baseline, and allocation to intervention and which may be randomised, quasi randomised or non-randomised), assessment of outcomes and generation of hypotheses (Higgins & Green, 2008).
B. Non-randomised studies (the use of detention has occurred in the course of usual decisions, the allocation to detention and non-detention is not controlled by the researcher and there is a comparison of two or more groups of participants. Participants are allocated by means such as time differences, location differences, decision makers or policy rules).

3.1.2 Types of participants

The “intervention population” are asylum seekers who have been detained. The comparison population are asylum seekers who have not been detained. Asylum seekers whose asylum application has not been successful will also be included. We will include asylum seekers of all ages and nationalities.

According to the United Nations Convention relating to the Status of Refugees as amended by its 1967 Protocol (the Refugee Convention, 1967), a refugee is a person who is outside their own country and is unable or unwilling to return due to a well-founded fear of being persecuted because of their race, religion, nationality, membership of a particular social group or political opinion (UNHCR, 2010).

The terms “asylum seeker” and “refugee” are often used interchangeably. We will follow UNHCR’s definition and use the term “asylum seeker” to mean an individual who has sought international protection and whose claim for refugee status has not yet been determined. As part of its obligation to protect refugees on its territory, the country of asylum is normally responsible for determining whether an asylum-seeker is a refugee or not. This responsibility is often incorporated in the national legislation of the country and, for State Parties, is derived from the 1951 Convention Relating to the Status of Refugees (UNHCR, 2011). Only after the recognition of the asylum seeker’s protection needs, can he or she officially be referred to as a refugee and enjoy refugee status, which carries certain rights and obligations according to the legislation of the receiving country.

3.1.3 Types of interventions

The intervention is the detention of asylum seekers, defined as the deprivation of liberty (personal freedom are being taken away) for asylum seekers in the host country. Studies investigating returned asylum seekers who are detained in their home country (due to having applied for asylum) will not be included. In most countries, the detention of asylum seekers is an administrative procedure and domestic legal systems rarely detail the detention situations. Detention of asylum seekers may be undertaken to verify the identity of individuals, process asylum
claims, and/or ensure that a deportation order is carried out. The detained may be held in various detention facilities (immigration holding centres, remote camps or provincial jails which may be run by public authorities or private companies).

3.1.4 **Types of outcomes**

All outcomes (e.g. mental health, physical health and social functioning) reported in studies using a comparable control group will be included and examined. The primary focus is on measures of mental health.

Examples of mental health outcomes include PTSD, depression, anxiety, and mental health-related disability which may be measured by standardized psychological symptom measures such as The Harvard Trauma Questionnaire, the Hopkins Symptom Checklist and the Medical Outcomes Study – Short Form. Results for mental health outcomes (PTSD, depression, anxiety, and mental health-related disability) will be analysed separately.

Examples of physical health outcomes include complaints about pain, gastrointestinal symptoms, and weight and hair loss measured by self-report or by reports by health authorities.

Social functioning outcomes include family functioning (e.g., measured by the Beavers Interactional Competence Scale; Beavers & Hampson, 2000), income, violence, crime, alcohol, and substance abuse measured by self-report, by reports by authorities, derived from administrative files or registers, or from results of biochemical test for drug and alcohol use.

Time points for measures considered will be:

- Participants currently detained
- From the end of detention to one year after release
- More than one year after release

## 3.2 SEARCH METHODS FOR IDENTIFICATION OF STUDIES

### 3.2.1 **Electronic searches**

Relevant studies will be identified through electronic searches of bibliographic databases, research networks, government policy databanks and internet search engines. No language or date restrictions will be applied to the searches.
The following databases will be searched:

**International**
- Academic Search Premier (multi-disciplinary)
- International Bibliography of Social Sciences (social science)
- IZA - Database for Migration Literature (http://www.iza.org/en/webcontent/links/migration)
- PILOTS (Published International Literature On Traumatic Stress)
- ProQuest dissertation & theses A&I
- PsycINFO (psychological science)
- PubCentral (medical, full-text)
- PubMed (medical science)
- Science Citation Index (science and technology journals)
- Social Science Citation Index (social science journals)
- SocINDEX (social science)
- The Cochrane Library (Cochrane reviews, other reviews with a medical focus)

**European/Scandinavian**
- Bibliotek.dk (provides access to the Danish national bibliography)
- Bibsys.no (the Norwegian library service for universities and university colleges)
- Libris.kb.se (the Swedish library service, providing access to 170 university and research libraries)
- RX Dignity – Danish Institute against Torture (related to refugees and torture)
- Social Care Online (UK database, social science)

### 3.2.2 Search terms

An example of the search strategy for PsycINFO is listed below. The strategy will be modified for the different databases. Both subject headings and text words will be searched.

1. asylum adj1 seek*.ti,ab.
3. “Asylum applicant*”.ti,ab.
4. “Asylum claim*”.ti,ab.
5. Exile*.ti,ab.
6. Fugitive*.ti,ab.
8. (Refuge* or Migrant* or Immigrant*.ti,ab.) or Refugees/

9.1-8/OR

10. Detention.ti,ab.
11. Confin*
12. Depriv* N2 liberty.ti,ab.
15. Restrain*.ti,ab.
16. Restrained.ti,ab.
17. Confine.ti,ab.
18. Confined.ti,ab.
20. Imprison*.ti,ab.
22. “Reception cent*”.ti,ab.
23. “Asylum cent*”.ti,ab.
26. Retention.ti,ab.
27. “refugee camp*”
29. Prison*.ti,ab. or prisons/

31. 10-30/OR

32. 9 AND 31

### 3.2.3 Searching other resources

**Hand searching**

The top five most represented journals in the database search will be hand searched for the years 2012 and 2013.
Reference lists of included studies and relevant reviews will be searched for potential literature

**Grey literature**
We will perform a general web search using Google and Google Scholar to identify potential unpublished studies and will screen the first 200 hits from Google. To help ensure an exhaustive search of the grey literature, we will screen all hits obtained from the Google Scholar search.

OpenGrey will be searched to identify potential European grey literature ([http://www.opengrey.eu/](http://www.opengrey.eu/)).

SSRN – Social Science Research Network ([www.ssrn.com](http://www.ssrn.com)) will be searched to identify working-papers and discussion-papers.

We will search the publications of the WHO, the World Bank and Amnesty international for relevant publications and will contact the authors for further information and suggestions for other studies or reports. We will also contact a key informant from each of these organizations for further information. Where available, advanced search options will be used to refine the grey search strategy.

Copies of relevant documents from Internet-based sources will be made. We will record the exact URL and date of access.

**Personal contacts**
Personal contacts will be made with national and international researchers and other experts in the field in attempt to identify unpublished reports, government documents and on-going studies.

### 3.3 METHODS USED IN PRIMARY STUDIES

Studies of the effect of detention are required to have a control group for inclusion in the review. An example of a study that may be included is Thompson and McGory (1998) who compared a group of 25 detained Tamil asylum seekers with a community-based group of Tamil asylum seekers. Another example is a study based
on a population of Mandaean refugees in Australia (Steel et al, 2006). Using snowball sampling techniques, the authors recruited 241 participants of which 62% had a history of asylum detention and had been released, on average, 3 years previously.

The primary studies must demonstrate pre-treatment group equivalence via matching, statistical controls, or evidence of equivalence on key risk variables and participant characteristics. The methodological appropriateness will be assessed according to the risk of bias model outlined in section 3.4.3. The risk of bias assessment makes it possible to discriminate between studies with varying degrees of risk. Studies that have been coded with a very high risk of bias (5 on the risk of bias scale) will not be included in the data synthesis.

### 3.4 DATA COLLECTION AND ANALYSIS

#### 3.4.1 Selection of studies

Two reviewers (TF, ML) will independently read titles and available abstracts of reports and articles identified in the search to exclude reports that are clearly irrelevant. Citations considered relevant by at least one reviewer will be retrieved in full text versions. If there is not enough information in the title and abstract to judge eligibility, the full text will be retrieved. At least two reviewers (TF, ML) will read the full text versions to ascertain eligibility based on the selection criteria. In the first screening level a citation will only move on to the second screening level if the answer is a ‘yes’ or ‘uncertain’ for the following criteria; (1) Does the study focus on the detention of asylum seekers? (2) Are the participants detained asylum seekers? (3) Is the report/article a quantitative evaluation study?

In the second screening level eligibility inclusion criteria is extended to the following; (4) Does the study compare detained asylum seekers with non-detained peers?

The inclusion coding questions for level 1 and 2 will be piloted and adjusted if required (see appendix 9.1) and changes will be reported. Primary investigators will be contacted to clarify study eligibility if necessary. In the event of disagreements, a third reviewer and content specialist (EM, MK) will be consulted to obtain a consensus. Disagreements resolved by a third reviewer will be reported. Exclusion reasons for studies that otherwise might be expected to be eligible will be documented and presented in an appendix. The overall search and screening process
will be illustrated in a flow-diagram. None of the review authors will be blind to the authors, institutions, or the journals responsible for the publication of the articles.

3.4.2 **Data extraction and management**

At least two review authors (TF, ML) will independently code and extract data from the included studies. Data and information will be extracted on: Available characteristics of participants, intervention characteristics and control conditions, research design, sample size, risk of bias and potential confounding factors, outcomes, and results. A data extraction sheet will be piloted on several studies and revised as necessary (see appendix 9.2) and changes will be reported. Extracted data will be stored electronically. Disagreements will be resolved by consulting a third review author with extensive content and methods expertise (EM, MK). Disagreements resolved by a third reviewer will be reported. Analysis will be conducted in RevMan5, SAS and Stata.

3.4.3 **Assessment of risk of bias in included studies**

We will assess the methodological quality of studies using a risk of bias model developed by Prof. Barnaby Reeves in association with the Cochrane Non-Randomised Studies Methods Group.\(^7\) This model is an extension of the Cochrane Collaboration’s risk of bias tool and covers risk of bias in non-randomised studies that have a well-defined control group.

The extended model is organised and follows the same steps as the existing risk of bias model according to the Cochrane Hand book, chapter 8 (Higgins & Green, 2008). The extension to the model is explained in the three following points:

1) The extended model specifically incorporates a formalised and structured approach for the assessment of selection bias in non-randomised studies by adding an explicit item about confounding. This is based on a list of confounders considered to be important and defined in the protocol for the review. The assessment of confounding is made using a worksheet where, for each confounder, it is marked whether the confounder was considered by the researchers, the precision with which it was measured, the imbalance between groups, and the care with which adjustment was carried out (see appendix 9.3). This assessment will inform the final risk of bias score for confounding.

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\(^7\)This risk of bias model was introduced by Prof. Reeves at a workshop on risk of bias in non-randomised studies at SFI Campbell, February 2011. The model is a further development of work carried out in the Cochrane Non-Randomised Studies Method Group (NRSMG).
2) Another feature of non-randomised studies that make them at high risk of bias is that they need not have a protocol in advance of starting the recruitment process. The item concerning selective reporting therefore also requires assessment of the extent to which analyses (and potentially, other choices) could have been manipulated to bias the findings reported, e.g., choice of method of model fitting, potential confounders considered / included. In addition, the model includes two separate yes/no items asking reviewers whether they think the researchers had a pre-specified protocol and analysis plan.

3) Finally, the risk of bias assessment is refined, making it possible to discriminate between studies with varying degrees of risk. This refinement is achieved with the addition of a 5-point scale for certain items (see the following section, Risk of bias judgement items for details).

The refined assessment is pertinent when thinking of data synthesis as it operationalizes the identification of studies (especially in relation to non-randomised studies) with a very high risk of bias. The refinement increases transparency in assessment judgements and provides justification for not including a study with a very high risk of bias in the meta-analysis.

Risk of bias judgement items

The risk of bias model used in this review is based on nine items (see appendix 9.3). The nine items refer to: sequence generation, allocation concealment, confounders, blinding, incomplete outcome data, selective outcome reporting, other potential threats to validity, a priori protocol and a priori analysis plan.

Confounding

An important part of the risk of bias assessment of non-randomised studies is how the studies deal with confounding factors (see appendix 9.3). Selection bias is understood as systematic baseline differences between groups and can therefore compromise comparability between groups. Baseline differences can be observable (e.g. age and gender) and unobservable (to the researcher; e.g. “appearance” of the asylum seeker). There is no single non-randomised study design that always deals adequately with the selection problem: Different designs represent different approaches to dealing with selection problems under different assumptions and require different types of data. There can be particularly great variations in how
different designs deal with selection on unobservables. The “adequate” method depends on the model generating participation, i.e. assumptions about the nature of the process by which participants are selected into a program. The primary studies must demonstrate pre-treatment group equivalence via matching, statistical controls, or evidence of equivalence on key risk variables and participant characteristics.

For this review, we have identified the following observable confounding factors to be most relevant: Prior trauma exposure, gender, age, time since arrival to the country where asylum is applied for and geographical/ethnic orientation. In each study, we will assess whether these confounding factors have been considered, and in addition we will assess other confounding factors considered in the individual studies. Furthermore, we will assess how each study deals with unobservables.

**Importance of pre-specified confounding factors**

The motivation for focusing on prior trauma exposure, gender, age, time spent in the country where asylum is applied for and geographical/ethnic orientation is given below.

**Prior trauma exposure**

It is very likely that the population under investigation in this review has been exposed to pre-migration traumatic events. Pre-migration trauma exposure is a major determinant for refugee mental health (Ichikawa, Nakahara & Wakai, 2006; Carswell, Blackburn & Barker, 2011).

In relation to the expected high pre-migration trauma exposure, gender and age are important factors to control for.

**Gender**

Women have been found to have higher prevalence rates of PTSD (Kessler, Sonnega, Bromet et al., 1995; Breslau, Kessler, Chilcoat, Schultz et al., 1998). However, this phenomenon can partly be explained by the different types of traumas men and women experience (Pratchett, Pelcovitz & Yehuda, 2010). According to Pratchett et al. (2010), women are more exposed to those types of trauma that are more likely to lead to PTSD symptoms, such as sexual assault. However, gender differences in exposure to different types of trauma cannot fully explain the gender differences in PTSD prevalence (Pratchett et al., 2010; Halligan & Yehuda, 2000; Gavranidou & Rosner, 2003), but no other firm explanation for gender differences exist (Halligan
& Yehuda, 2000). According to Gavranidou and Rosner (2003), the question of whether women are at higher risk of being diagnosed with PTSD is unresolved. Gender (being female) is however found to be a risk factor for other psychiatric disorders (Halligan & Yehuda, 2000).

Age
Given the different influences on development over the life course, particularly during the early years (Enlow et al, 2011; Lustig et al, 2003), age is a likely risk factor with respect to the consequences of exposure to trauma.

Time since arrival to the country where asylum is applied for
If the non-detained have stayed for longer in the asylum seeking country they also have had a longer timer to recover from possible pre-migration traumas than the detained and vice versa.

Geographical/ethnic orientation:
The ways of expressing distress and views of the causes differ in some cultures markedly from that of the dominant ‘Western’ culture. Furthermore, although similar symptoms may exist in different cultures, they do not necessarily have the same value or meaning.

Unobservables
For the “intervention” under consideration in this review, it is reasonable to expect a certain degree of arbitrariness in the decision process. If the criteria for detention are unclear it implies that whether or not an asylum seeker is detained is unpredictable. According to the Council of Europe (2010), national detention policies are non-transparent. Detention of asylum seekers is often applied in a way that is unlawful or arbitrary and can be arbitrarily prolonged, for example if there is no practical and imminent possibility of removal. In general, detainees have difficulty challenging the legality of their detention (Welch & Schuster, 2005; Amaral, 2010; Council of Europe, 2010).

Although arbitrariness is not randomness, we will assess the degree of arbitrariness in the detention decision process as described by the authors. The risk of systematic differences in unobservable factors between those detained or not detained will probably be minimized if there is a high degree of arbitrariness in the decision process.

Assessment
Review authors (at least two, TF & ML) will independently assess the risk of bias for each included study. Disagreements will be sought by a third reviewer with content and statistical expertise (EM, MK). We will report the risk of bias assessment in risk of bias tables for each included study in the completed review.

3.4.4 **Measures of treatment effect**

*Continuous outcomes*

For continuous outcomes, effects sizes with 95% confidence intervals will be calculated, where means and standard deviations are available. If means and standard deviations are not available, the review authors will request this information from the principal investigators. If no information is yielded, we will calculate SMDs from F-ratios, t-values, chi-squared values and correlation coefficients, where available, using the methods suggested by Lipsey & Wilson (2001). Hedges' $g$ will be used for estimating standardized mean differences (SMD). Any scales related to mental health (e.g. PTSD, anxiety, depression, etc.), income, alcohol, and substance abuse are examples of relevant continuous outcomes in this review.

*Dichotomous outcomes*

For dichotomous outcomes, we will calculate odds ratios with 95% confidence intervals. Physical health outcomes (e.g. complaints about pain, gastrointestinal symptoms and weight and hair loss) and crime are examples of relevant dichotomous outcomes in this review.

The mental health outcomes, alcohol and substance abuse may be reported as mean symptom scores or numbers diagnosed, i.e. numbers meeting cut off scores.

There are statistical approaches available to re-express dichotomous and continuous data to be pooled together (Sánchez-Meca, Marín-Martínes & Chacón-Moscoso, 2003). In order to calculate common metric odds, ratios will be converted to SMD effect sizes using the Cox transformation. We will only transform dichotomous effect sizes to SMD if appropriate, e.g., as may be the case with the outcomes PTSD, anxiety, depression, etc. that can be measured with binary and continuous data.

When effect sizes cannot be pooled, study-level effects will be reported in as much detail as possible. Software for storing data and statistical analyses will be RevMan 5.0, Excel and Stata 10.0.
3.4.5 Unit of analysis issues

We will take into account the unit of analysis of the studies to determine whether individuals may have undergone multiple interventions, whether there were multiple treatment groups and whether several studies are based on the same data source.

Multiple interventions groups and multiple interventions per individuals

Multiple intervention groups within a study with one control group will be pooled if appropriate (if they include different individuals) and compared to that control group. Multiple controls groups will only be pooled if appropriate (if they include different individuals).

A synthetic (average) effect size will be calculated and used to avoid dependence problems. This method provides an unbiased estimate of the mean effect size parameter but overestimates the standard error. Random effects models applied when synthetic effect sizes are involved actually perform better in terms of standard errors than do fixed effects models (Hedges, 2007). However, tests of heterogeneity when synthetic effect sizes are included are rejected less often than nominal.

If pooling is not appropriate (e.g., the multiple interventions and/or control groups include the same individuals), only one intervention group will be coded and compared to the control group to avoid overlapping samples. The choice of which estimate to include will be based on our risk of bias assessment. We will choose the estimate that we judge to have the least risk of bias (primarily, degree of selection bias and, in case of equal bias, the group with more complete data will be used).

Multiple studies using the same sample of data

In some cases, several studies may have used the same sample of data. We will review all such studies, but in the meta-analysis we will only include one estimate of the effect from each sample of data. This will be done to avoid dependencies between the “observations” (i.e. the estimates of the effect) in the meta-analysis. The choice of which estimate to include will be based on our risk of bias assessment of the studies. We will choose the estimate from the study that we judge to have the least risk of bias (primarily, selection bias).

Multiple time points
When the results are measured at multiple time points, each outcome at each time point will be analysed in a separate meta-analysis with other comparable studies taking measurements at a similar time point. As a general guideline, these will be grouped together as follows: 1) Participants currently detained, 2) From the end of detention to one year after release, and 3) More than one year after release. However, should the studies provide viable reasons for an adjusted choice of relevant and meaningful duration intervals for the analysis of outcomes, we will adjust the grouping.

3.4.6 **Dealing with missing and incomplete data**

Missing data and attrition rates will be assessed in the included studies; see section 3.4.3. Where studies have missing summary data, such as missing standard deviations, the review authors will request this information from the principal investigators. If no information is yielded, we will derive these where possible from F-ratios, t-values, chi-squared values and correlation coefficients using the methods suggested by Lipsey & Wilson (2001). If missing summary data cannot be derived, the study results will be reported in as much detail as possible.

3.4.7 **Assessment of heterogeneity**

Heterogeneity among primary outcome studies will be assessed with Chi-squared (Q) test, and the I-squared, and τ-squared statistics (Higgins, Thompson, Deeks, & Altman, 2003). Any interpretation of the Chi-squared test will be made cautiously on account of its low statistical power.

3.4.8 **Assessment of reporting bias**

Reporting bias refers to both publication bias and selective reporting of outcome data and results. Here, we state how we will assess publication bias.

We will use funnel plots for information about possible publication bias if we find sufficient studies (Higgins & Green, 2008). However, asymmetric funnel plots are not necessarily caused by publication bias (and publication bias does not necessarily cause asymmetry in a funnel plot). If asymmetry is present, we will consider possible reasons for this.
3.5 DATA SYNTHESIS

Studies that have been coded with a very high risk of bias (5 on the risk of bias scale) will not be included in the data synthesis.

All follow-up durations reported in the primary studies will be recorded and we will do separate analyses for short-term and long-term outcomes.

Otherwise included studies will be pooled. As we expect the primary studies to deal with diverse populations of participants, the choice of a random model to represent the overall effect seems to be the most adequate option. For subsequent analyses of moderator variables in the search for systematic variations, we will switch to the mixed model (if a predictor that explains some between-studies variation is available) but as we also want to account for the remaining uncertainty, the mixed-effects regression model is appropriate (Hedges and Pigott, 2004; Konstantopoulos, 2006).

In some cases, several studies may have used the same sample of data. We will review all such studies, but in the meta-analysis we will only include one estimate of the detention effect from each sample of data. This will be done to avoid dependencies between the “observations” (i.e. the estimates of the effect) in the meta-analysis. The choice of which estimate to include will be based on our quality assessment of the studies. We will choose the estimate from the study that we judge to have the least risk of bias, with particular attention paid to selection bias.

3.5.1 Moderator analysis and investigation of heterogeneity

We will investigate the following factors with the aim of explaining observed heterogeneity: Study-level summaries of participant characteristics (studies considering a specific age group or gender, or studies where separate effects for men/women or young/old are available), rate of pre-migration trauma exposure, and length of detention.

If the number of included studies is sufficient (at least 10 degrees of freedom) and given there is variation in the covariates, we will perform moderator analyses (multiple meta-regression using the mixed model) to explore how observed variables are related to heterogeneity. We will estimate the (new) residual variance component to be used in a weighted least squares analysis conditional on this
variance component estimate. The residual variance component will be estimated using the method-of-moments estimator (Hartung, Knapp & Sinha, 2008; Konstantopoulos, 2006). We will report 95% confidence intervals for regression parameters. We will estimate the correlations between the covariates and consider the possibility of confounding. Conclusions from meta-regression analysis will be cautiously drawn and will not be based on significance tests.

Otherwise, single factor subgroup analysis will be performed. The assessment of any difference between subgroups will be based on 95% confidence intervals. Interpretation of relationships will be cautious, as they are based on subdivision of studies and indirect comparisons.

In general, the strength of inference regarding differences in treatment effects among subgroups is controversial. However, making inferences about different effect sizes among subgroups on the basis of between-study differences entails a higher risk compared to inferences made on the basis of within study differences; see Oxman & Guyatt (1992). We will therefore use within study differences where possible.

We will also consider the degree of consistence of differences, as making inferences about different effect sizes among subgroups entails a higher risk when the difference is not consistent within the studies; see Oxman & Guyatt (1992).

### 3.5.2 Sensitivity analysis

Sensitivity analysis will be carried out by restricting the meta-analysis to a subset of all studies included in the original meta-analysis and will be used to evaluate whether the pooled effect sizes are robust across components of methodological quality. For methodological quality, we will consider sensitivity analysis for each major component of the risk of bias checklists and restrict the analysis to studies with a low risk of bias.

Sensitivity analysis will further be used to examine the strength of conclusions in relation to any pooling of results from multiple intervention groups.
4 Sources of support

4.1 INTERNAL SOURCES

SFI Campbell

4.2 EXTERNAL SOURCES

DIGNITY and Videnscenter om transkulturel psykiatri
Filges, Lindstrøm, Montgomery and Kastrup contributed to the writing and revising of this protocol. The search strategy was developed by Filges and Hansen.
6 Acknowledgements

We very much appreciate the work done by Pia Vang Hansen in the development of the search strategy.
7 Potential conflicts of interest

The authors have no vested interest in the outcomes of this review, nor any incentive to represent findings in a biased manner.
References


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JRS Europe (2012). Policy position on alternatives to detention. Available from URL: [http://www.refworld.org/pdfid/50ac9c0f2.pdf](http://www.refworld.org/pdfid/50ac9c0f2.pdf) (accessed 19 September 2013)


http://parlinfo.aph.gov.au/parlInfo/download/library/prspub/5P1X6/upload_binary/5P1X6.pdf;fileType=application/pdf#search=%22boat%20arrivals%20in%20Australia%20since%22


Regional resettlement arrangement between Australia and Papua New Guinea [Australia], 19 July 2013, available at:


United Nations High Commissioner for Refugees. (2013), Australia-Papua New Guinea asylum agreement presents protection challenges, Briefing Notes, 26 July 2013


9 Appendices

9.1 FIRST AND SECOND LEVEL SCREENING

First level screening is on the basis of titles and abstracts. Second level is on the basis of full text.

Reference id. No. :
Study id. No.:
Reviewer’s initials:
Source:
Year of publication:
Duration of study:
Country/countries of origin:
Author:

The study is excluded if one or more of the answers to questions 1-3 (below) is ‘No’. If the answers to questions 1 to 3 are ‘yes’ or ‘uncertain’, then the full study is retrieved for second level eligibility. All uncertain questions need to be posed again on the basis of full text. If not enough information is available or if the study is unclear, the author of the study will be contacted if possible.

First level screening questions are based on titles and abstracts

1. Does the study focus on the detention of asylum seekers?
   Yes - include
   No – if no then stop here and exclude
   Uncertain - include

Question 1 guidance:
The intervention is the detention of asylum seekers, defined as the deprivation of liberty for asylum seekers. Notice that the terms “asylum seeker” and “refugee” are often used interchangeably.

2. Are the participants detained asylum seekers?
   Yes - include
   No – if no then stop here and exclude
   Uncertain - include

Question 2 guidance:
Asylum seekers whose asylum application has not been successful will also be included.

3. Is this study a primary quantitative study?
   Yes - include
   No – if no then stop here and exclude
   Uncertain - include

Question 3 guidance:
We are only interested in primary quantitative studies, where the authors have analyzed the data. We are not interested in qualitative papers on the topic or surveys/reviews of studies of the topic. (This question may be difficult to answer based on titles and abstracts alone).

**Second level screening questions based on full text**

4. Does the study compare detained asylum seekers to nondetained peers?
   Yes - include
   No – if no then stop here and exclude
   Uncertain - include

Question 4 guidance
Include all study designs that use a well-defined control group as, for example, asylum seekers in the same country who are not detained.

9.2 DATA EXTRACTION
<table>
<thead>
<tr>
<th>Names of author(s)</th>
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</thead>
<tbody>
<tr>
<td>Title</td>
<td></td>
</tr>
<tr>
<td>Language</td>
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<td>Journal</td>
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<td>Year</td>
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<td>Country</td>
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<td>Participant characteristics (age, gender, geographical/ethnic origin, legal status)</td>
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<td>Time period covered by analysis</td>
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<td>Sample size</td>
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<td>Sampling technique</td>
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<td>Type of data used in study (administrative, questionnaire, other (specify))</td>
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<tr>
<td>Intervention characteristics available (place of detention, living conditions, access to legal assistance, information, health care services and psychological support)</td>
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<tr>
<td>Length of detention</td>
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<tr>
<td>Prior trauma exposure/experiences</td>
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<tr>
<td>Time since arrival to the country where asylum is applied for</td>
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</tbody>
</table>
**Outcome measures**
Instructions: Please enter outcome measures in the order in which they are described in the report. Note that a single outcome measure can be completed by multiple sources and at multiple points in time (data from specific sources and time-points will be entered later).

<table>
<thead>
<tr>
<th>#</th>
<th>Outcome &amp; measure</th>
<th>Reliability &amp; Validity</th>
<th>Format</th>
<th>Direction</th>
<th>Pg# &amp; notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>Info from:</td>
<td>Dichotomy</td>
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<td>Other samples</td>
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<td>This sample</td>
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* Repeat as needed
### OUTCOME DATA

#### DICHTOMOUS OUTCOME DATA

<table>
<thead>
<tr>
<th>OUTCOME</th>
<th>TIME POINT (s) (record exact time from participation, there may be more than one, record them all)</th>
<th>SOURCE</th>
<th>VALID Ns</th>
<th>CASES</th>
<th>NON-CASES</th>
<th>STATISTICS</th>
<th>Pg. # &amp; NOTES</th>
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</thead>
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<td></td>
<td>Questionnaire Admin data Other (specify) Unclear</td>
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<td></td>
<td></td>
<td>RR (risk ratio) OR (odds ratio) SE (standard error) 95% CI DF</td>
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<td>Participation Participation</td>
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<td>P- value (enter exact p value if available) Chi2 Other</td>
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</table>

Repeat as needed
## CONTINUOUS OUTCOME DATA

<table>
<thead>
<tr>
<th>OUTCOME</th>
<th>TIME POINT (s) (record exact time from participation, there may be more than one, record them all)</th>
<th>SOURCE (specify)</th>
<th>VALID Ns</th>
<th>Means</th>
<th>SDs</th>
<th>STATISTICS</th>
<th>Pg. # &amp; NOTES</th>
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<tr>
<td>Questionnaire Admin data Other (specify) Unclear</td>
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*Repeat as needed*
## 9.3 Assessment of Risk of Bias in Included Studies

### Risk of bias table

<table>
<thead>
<tr>
<th>Item</th>
<th>Judgement</th>
<th>Description (quote from paper, or describe key information)</th>
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<tbody>
<tr>
<td>1. Sequence generation</td>
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<tr>
<td>2. Allocation concealment</td>
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<td></td>
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<tr>
<td>3. Confounding*b,c</td>
<td></td>
<td></td>
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<tr>
<td>4. Blinding?b</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Incomplete outcome data addressed?b</td>
<td></td>
<td></td>
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<tr>
<td>6. Free of selective reporting?b</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Free of other bias?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. A priori protocol?d</td>
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<tr>
<td>9. A priori analysis plan?e</td>
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<td></td>
</tr>
</tbody>
</table>

*a Some items on low/high risk/unclear scale (double-line border), some on 5 point scale/unclear (single line border), some on yes/no/unclear scale (dashed border). For all items, record “unclear” if inadequate reporting prevents a judgement being made.

*b For each outcome in the study.

*c This item is only used for NRCTs and NRSs. It is based on a list of confounders considered as important at the outset and defined in the protocol for the review (assessment against worksheet).

*d Did the researchers write a protocol defining the study population, intervention and comparator, primary and other outcomes, data collection methods, etc. in advance of starting the study?

*e Did the researchers have an analysis plan defining the primary and other outcomes, statistical methods, subgroup analyses, etc. in advance of starting the study?
Risk of bias tool

Studies for which RoB tool is intended
The risk of bias model is developed by Prof. Barnaby Reeves in association with the Cochrane Non-Randomised Studies Methods Group. This model, an extension of the Cochrane Collaboration’s risk of bias tool, covers both risk of bias in randomised controlled trials (RCTs and QRCTs), but also risk of bias in non-randomised studies (NRCTs and NRSs).

The point of departure for the risk of bias model is the Cochrane Handbook for Systematic Reviews of Interventions (Higgins & Green, 2008). The existing Cochrane risk of bias tool needs elaboration when assessing non-randomised studies because, for non-randomised studies, particular attention should be paid to selection bias / risk of confounding. Additional items on confounding are used only for non-randomised studies (NRCTs and NRSs) and are not used for randomised controlled trials (RCTs and QRCTs).

Assessment of risk of bias
Issues when using modified RoB tool to assess included non-randomised studies:

- Use existing principle: score judgment and provide information (preferably direct quote) to support judgment.
- Additional items on confounding used only for non-randomised studies (NRCTs and NRSs).
- 5-point scale for some items (distinguish “unclear” from intermediate risk of bias).
- Keep in mind the general philosophy – assessment is not about whether researchers could have done better but about risk of bias; the assessment tool must be used in a standard way irrespective of the difficulty / circumstances of investigating the research question of interest or the study design used.
- Anchors: “1/No/low risk” of bias should correspond to a high quality RCT. “5/high risk” of bias should correspond to a risk of bias that means the findings should not be considered (too risky, too much bias, more likely to mislead than inform).

1. Sequence generation
   - Low/high/unclear RoB item.
   - Always high RoB (not random) for a non-randomised study.
   - Might argue that this item is redundant for NRS since it is always high – but it is important to include it in an RoB table (‘level playing field’ argument).

2. Allocation concealment
   - Low/high/unclear RoB item.
   - Potentially low RoB for a non-randomised study, e.g. quasi-randomised (too high RoB to sequence generation) but concealed (reviewer judges that the people making decisions about including participants didn’t know how allocation was being done, e.g. odd/even date of birth/hospital number).

3. RoB from confounding (additional item for NRCT and NRS; assess for each outcome)
   - Assumes a pre-specified list of potential confounders defined in the protocol
   - Low(1) / 2 / 3 / 4 / high(5) / unclear RoB item

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8 This risk of bias model was introduced by Prof. Reeves at a workshop on risk of bias in non-randomised studies at SFI Campbell, February 2011. The model is a further development of work carried out in the Cochrane Non-Randomised Studies Method Group (NRSMG).
• Judgment needs to factor in:
  o proportion of confounders (from pre-specified list) that were considered
  o whether most important confounders (from pre-specified list) were considered
  o resolution/precision with which confounders were measured
  o extent of imbalance between groups at baseline
  o care with which adjustment was done (typically a judgment about the statistical modeling carried out by authors)

• Low RoB requires that all important confounders are balanced at baseline (not primarily/not only) a statistical judgment OR measured 'well' and 'carefully' controlled for in the analysis.

Assess against pre-specified worksheet. Reviewers will make an RoB judgment about each factor first and then 'eyeball' these for the judgment RoB table.

4. RoB from lack of blinding (assess for each outcome, as per existing RoB tool)
   • Low(1) / 2 / 3 / 4 / high(5) / unclear RoB item
   • Judgment needs to factor in:
     o nature of outcome (subjective / objective; source of information)
     o who was / was not blinded and the risk that those who were not blinded could introduce performance or detection bias
     o see Ch.8

5. RoB from incomplete outcome data (assess for each outcome, as per existing RoB tool)
   • Low(1) / 2 / 3 / 4 / high(5) / unclear RoB item
   • Judgment needs to factor in:
     o reasons for missing data
     o whether amount of missing data balanced across groups, with similar reasons
     o whether censoring is less than or equal to 25% and has been taken into account
     o see Ch.8

6. RoB from selective reporting (assess for each outcome, NB different to existing Ch.8 recommendation)
   • Low(1) / 2 / 3 / 4 / high(5) / unclear RoB item
   • Judgment needs to factor in:
     o existing RoB guidance on selective outcome reporting (see Ch.8)
     o also, extent to which analyses (and potentially other choices) could have been manipulated to bias the findings reported, e.g. choice of method of model fitting, potential confounders considered / included
     o look for evidence that there was a protocol in advance of doing any analysis / obtaining the data (difficult unless explicitly reported); NRS very different from RCTs. RCTs must have a protocol in advance of starting to recruit (for REC/IRB/other regulatory approval); NRS need not (especially older studies).
     o Hence, separate yes/no items asking reviewers whether they think the researchers had a pre-specified protocol and analysis plan.

7. RoB from other bias (assess for each outcome, NB different to existing Ch.8 recommendation)
   • Low(1) / 2 / 3 / 4 / high(5) / unclear RoB item
   • Judgment needs to factor in:
     o existing RoB guidance on other potential threats to validity (see Ch.8)
o also, assess whether suitable cluster analysis is used (e.g. cluster summary statistics, robust standard errors, the use of the design effect to adjust standard errors, multi-level models and mixture models), if assignment of units to treatment is clustered.
Confounding Worksheet

Assessment of how researchers dealt with confounding

<table>
<thead>
<tr>
<th>Method for identifying relevant confounders described by researchers:</th>
<th>yes</th>
<th>no</th>
</tr>
</thead>
<tbody>
<tr>
<td>If yes, describe the method used:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relevant confounders described:</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>List confounders described on next page</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Method used for controlling for confounding</td>
<td></td>
<td></td>
</tr>
<tr>
<td>At design stage (e.g. matching, regression discontinuity, instrument variable):</td>
<td></td>
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<tr>
<td></td>
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<tr>
<td>At analysis stage (e.g. stratification, regression, difference-indifference):</td>
<td></td>
<td></td>
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</tbody>
</table>

Describe confounders controlled for below

Confounders described by researchers

Tick (yes[0]/no[1] judgment) if confounder considered by the researchers [Considered]
Score (1[good precision] to 5[poor precision]) precision with which confounder measured
Score (1[balanced] to 5[major imbalance]) imbalance between groups
Score (1[very careful] to 5[not at all careful]) care with which adjustment for confounder was carried out

<table>
<thead>
<tr>
<th>Confounder</th>
<th>Considered</th>
<th>Precision</th>
<th>Imbalance</th>
<th>Adjustment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Geographical/ethnic orientation</td>
<td></td>
<td></td>
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<tr>
<td>Pre-migration trauma exposure</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time since arrival to the country where asylum is applied for</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unobservables⁹</td>
<td></td>
<td>Irrelevant</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

⁹ See user guide for unobservables
**User guide for unobservables**

Selection bias is understood as systematic baseline differences between groups and can therefore compromise comparability between groups. Baseline differences can be observable (e.g. age and gender) and unobservable (to the researcher; e.g. ‘appearance’). There is no single non-randomised study design that always solves the selection problem. Different designs solve the selection problem under different assumptions and require different types of data. There can be particularly great variations in how different designs deal with selection on unobservables. The “right” method depends on the model generating participation, i.e. assumptions about the nature of the process by which participants are selected into a programme.

As there is no universally correct way to construct counterfactuals, we will assess the extent to which the identifying assumptions (the assumption that makes it possible to identify the counterfactual) are explained and discussed (preferably by the authors in an effort to justify their choice of method). We will look for evidence of authors using the following examples (this is NOT an exhaustive list):

**Natural experiments:**
Discuss whether they face a truly random allocation of participants and that there is no change of behavior in anticipation of, e.g. policy rules.

**Instrumental variable (IV):**
Explain and discuss the assumption that the instrumental variable does not affect outcomes other than through their effect on participation.

**Matching (including propensity scores):**
Explain and discuss the assumption that there is no selection on unobservables, only selection on observables.

**(Multivariate, multiple) Regression:**
Explain and discuss the assumption that there is no selection on unobservables, only selection on observables. Further discuss the extent to which they compare comparable people.

**Regression Discontinuity (RD):**
Explain and discuss the assumption that there is a (strict!) RD treatment rule. It must not be changeable by the agent in an effort to obtain or avoid treatment. Continuity in the expected impact at the discontinuity point is required.

**Difference-in-difference (Treatment-control-before-after):**
Explain and discuss the assumption that outcomes of participants and nonparticipants evolve over time in the same way.