

Interpersonal Risk and Resilience in Child Diabetes Study (IRRiCD): Protocol

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1. Goals

To develop and test a theoretical model - the Interpersonal Risk and Resilience mechanisms in Child Diabetes model (IRRICD) - of how parents may influence outcomes in children with Type 1 Diabetes (T1D).

- To compare the level of parental fear/distress, parental behavior, and child outcomes between children with T1D and their parents, and a control sample of children and their parents from the general population.
- To investigate the impact of disease-specific parenting stress and general parental distress upon child outcomes (over time).
- To investigate the mediating role of parental protective behavior (protective parenting and hypoglycemia avoidance behavior) in the impact of parental fear/distress upon child outcomes.
- To investigate resilience mechanisms (parental trait mindfulness) that may buffer against the negative impact of parental fear/distress upon parent behavior and child outcomes.
- To explore differences between mothers and fathers in fear/distress levels, their impact upon child outcomes and the impact upon parental behaviors.

To reach those goals, the IRRiCD-study uses multiple methods:

1.1. Study A: Prospective questionnaire study (containing 4 waves)

- To compare children with T1D and their parents with a control sample from the general population on child outcomes and parental fear/distress, and parental behavior respectively.
- To examine the time course of parental distress, its impact upon child outcomes and the mediating role of parental behavior.

1.2. Study B: Diary study

- To capture the dynamics of diabetes symptoms, parental fear/distress, parental behavior, and child functioning from day to day.

1.3. Study C: Observational study

- To observe and investigate disease-specific parent-child interactions in the context of childhood T1D during a diabetes-specific situation (mealtime situations including blood glucose monitoring and insulin administration).
- To investigate associations between observed parent-child interactions, parental fear/distress, and parental trait mindfulness.

2. Recruitment: Clinical population

Recruitment procedure: Parents and their children with T1D were recruited through 6 Flemish hospitals: University Hospital Ghent, University Hospital Leuven, University Hospital Brussels, University Hospital Antwerp, General Hospital Sint-Jan in Bruges and Queen Paola Child Hospital Antwerp.

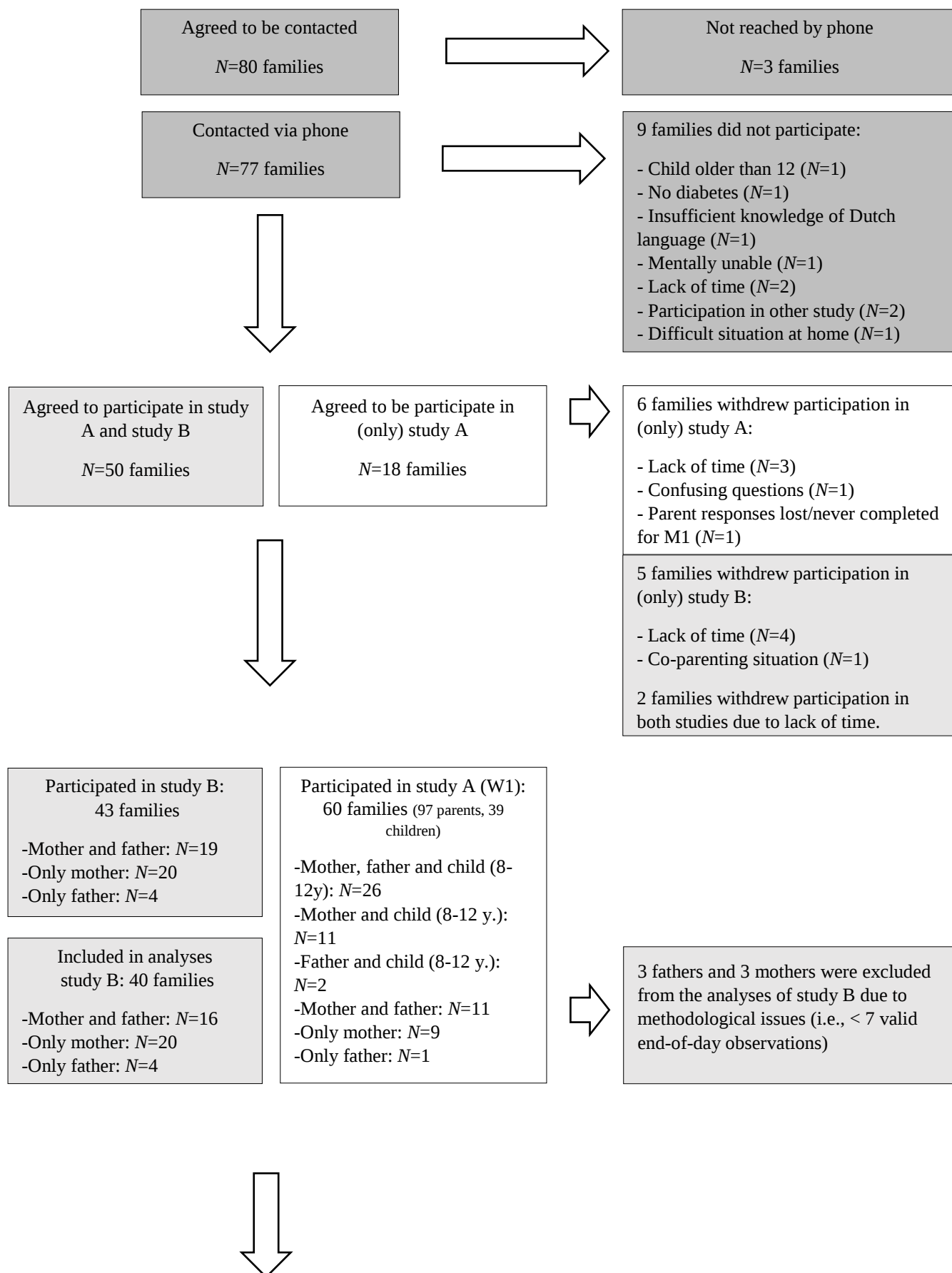
Inclusion criteria: (1) children being diagnosed with Type 1 diabetes for at least 6 months, (2) children aged between 2 and 12 years, (3) child (8-12 years) and parent having sufficient knowledge of the Dutch language and (4) child (8-12 years) and parent having sufficient mental abilities to complete the questionnaires.

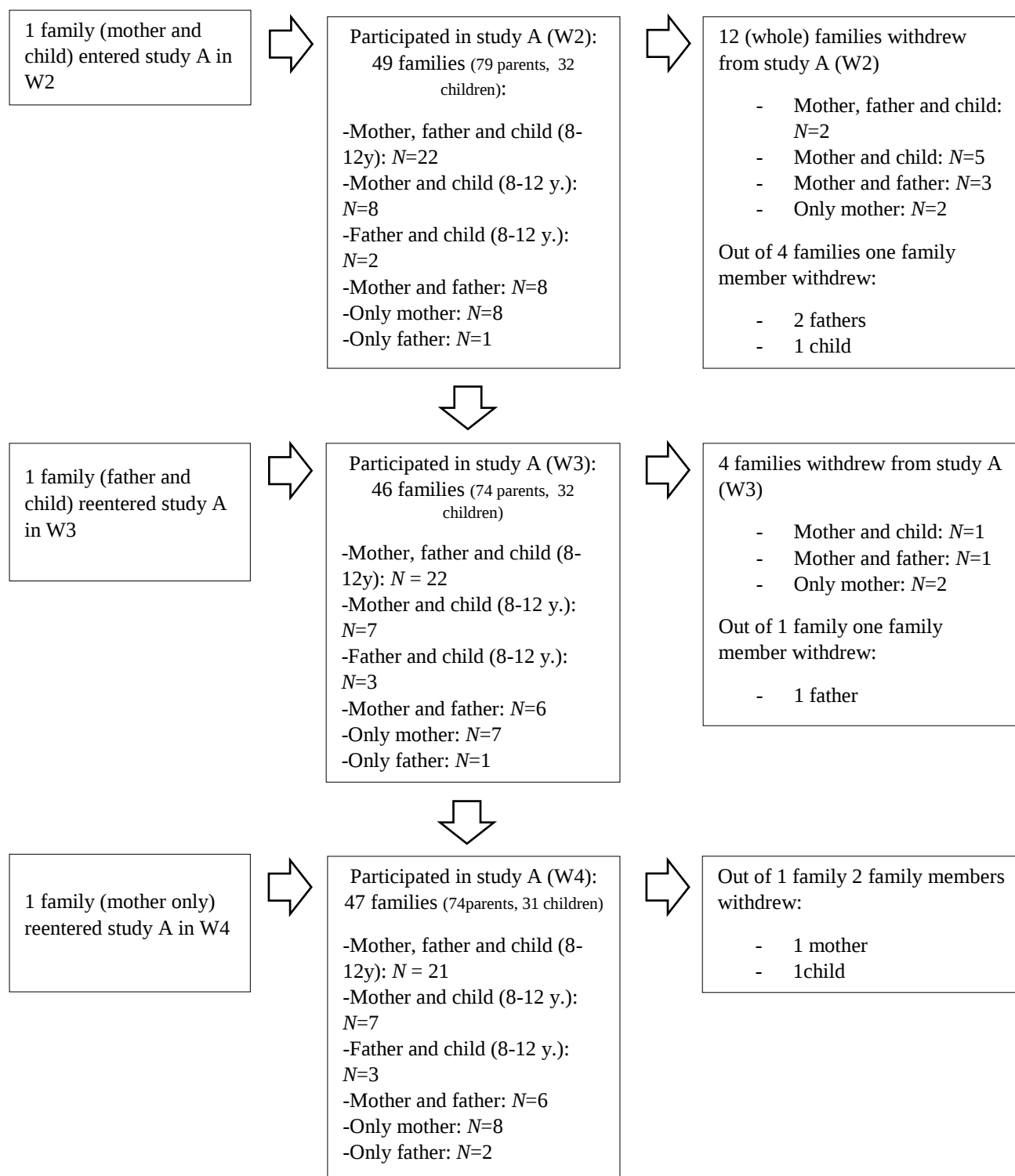
Recruitment was performed in three consecutive phases.

2.1. Recruitment phase 1: Prospective questionnaire study (A) and diary study (B)

All families who met the inclusion criteria and had a routine clinic visit in one of the four University Hospitals (Ghent, Leuven, Brussels and Antwerp) during the first phase of the recruitment procedure (July 2016 – November 2016 (Gent)/ January 2017 (Leuven, Brussels and Antwerp)) received information about the prospective questionnaire study and the diary study from their pediatrician. Families who agreed to be contacted ($N = 80$) were phoned by a research assistant and asked if they were willing to participate in (1) the prospective questionnaire study. If they agreed to participate in the prospective questionnaire study, they were also asked (2) whether they were willing to participate in the diary study. Eighteen families decided to only participate in the prospective questionnaire study. Fifty families agreed to participate in both studies. Later on, 11 families withdrew participation from one or both studies, for various reasons. Finally, 43 families (19 mother-father dyads, 20 mothers only, 4 fathers only) participated in the diary study. Due to methodological issues (i.e., < 7 valid end-of-day observations) 3 mothers and 3 fathers were excluded from the analyses, which resulted in a final sample of 40 families (16 mother-father dyads, 20 mothers only and 4 fathers only). Sixty families participated in the first wave of the prospective questionnaire study (mother, father and child ($N = 26$), mother and child: ($N = 11$), father and child: ($N = 2$), mother and father: ($N = 11$), only mother: ($N = 9$), only father: ($N = 1$)). In the second wave of the prospective questionnaire study, 49 families participated (mother, father and child ($N = 22$), mother and child: ($N = 8$), father and child: ($N = 2$), mother and father: ($N = 8$), only mother: ($N = 8$), only father: ($N = 1$)). Twelve families withdrew from the study after wave 1, and out of 4 families, one family member withdrew. One family entered the study in wave 2 (mother and child). Forty-six families participated in the third wave (mother, father and child ($N = 22$), mother and child: ($N = 7$), father and child: ($N = 3$), mother and father: ($N = 6$), only mother: ($N = 7$), only father: ($N = 1$)). Four families withdrew after wave 2, and out of one family, one family member withdrew from the study. One family (father and child) reentered the study in the third wave. In the final wave of the prospective questionnaire study, 47 families participated (mother, father and child ($N = 21$), mother and child: ($N = 7$), father and child: ($N = 3$), mother and father: ($N = 6$), only mother: ($N = 8$), only father: ($N = 2$)). Out of 1 family, 2 family members withdrew. One family reentered the study in wave 4 (mother).

Figure 1. Flow chart of recruitment during phase 1



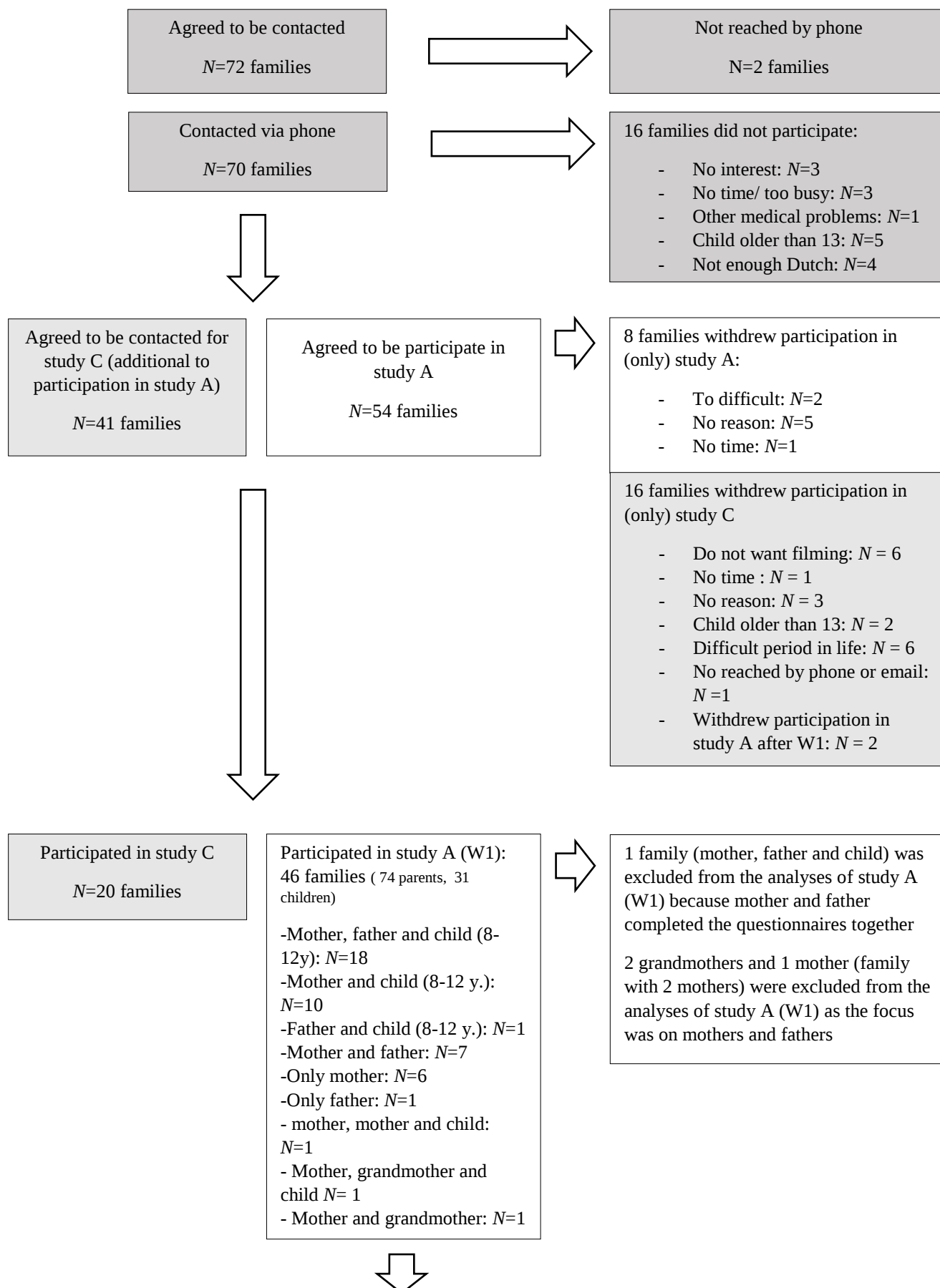


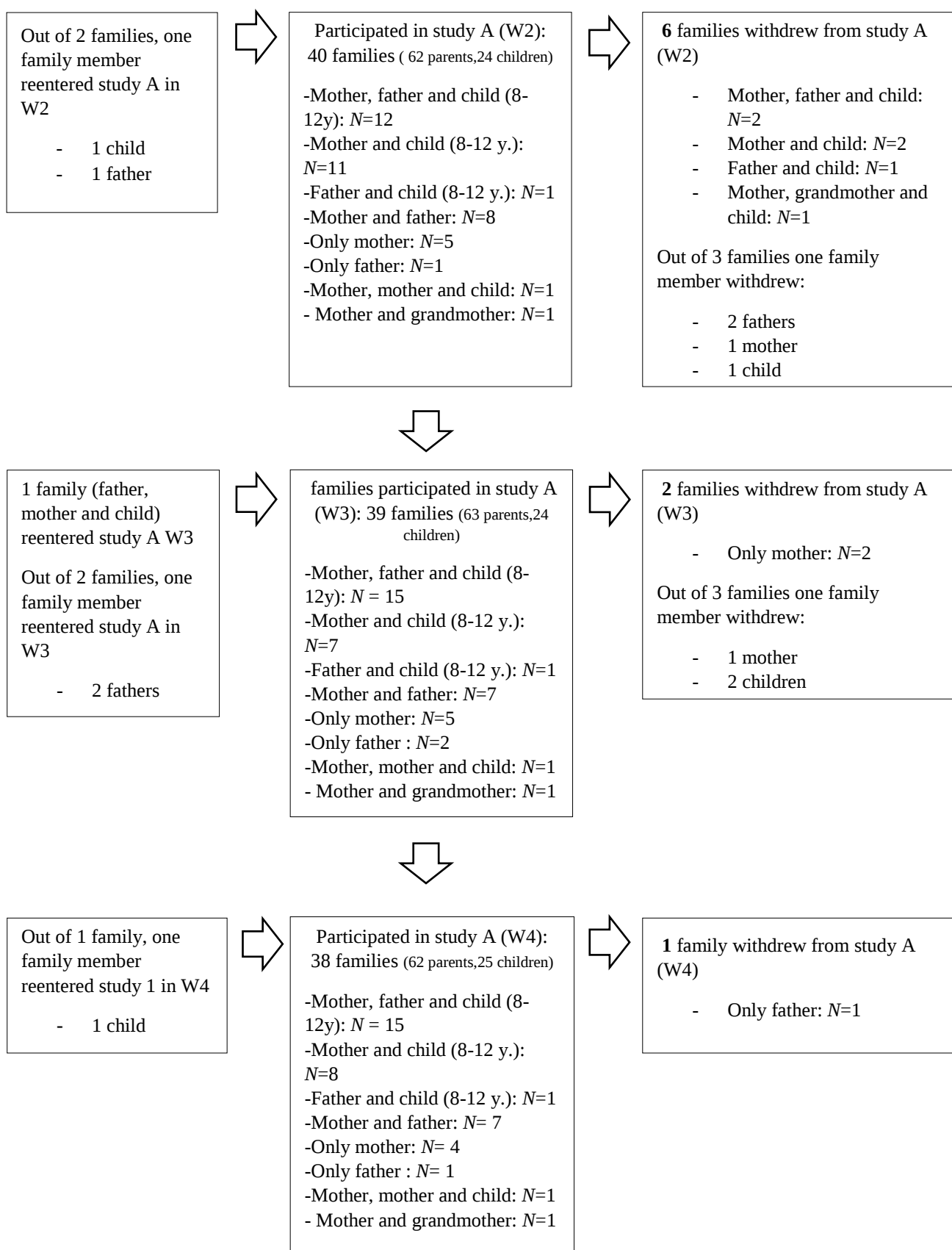
2.2. Recruitment phase 2: Prospective questionnaire study (A) and observation study (C)

The second phase of the recruitment procedure started in December 2016 in Ghent University Hospital, in February 2017 in the other University hospitals (Leuven, Brussels and Antwerp) and in May 2017 in Sint-Jan Hospital in Bruges and Queen Paola Child Hospital Antwerp. This phase ended in December 2017, as this was the deadline for inclusion in the prospective study. This deadline was set to make it possible for all participants to end the forth wave within the planned timeframe of the project.

All families who met the inclusion criteria and had a routine clinic visit in one of the six participating hospitals during the second phase of the recruitment procedure received information about the prospective questionnaire study and the observation study from their pediatrician. Families who agreed to be contacted ($N = 72$) were phoned by a research assistant and asked if they were willing to participate in (1) the prospective questionnaire study. If they agreed to participate in the prospective questionnaire study, they were also asked (2) whether they consented to be contacted for the observation study in a later phase. Fifty-four families agreed to participate in the prospective study, of which 41 additionally agreed to be contacted for the observation study. Later on, 24 families withdrew participation from one or both studies, for various reasons. Finally, 20 families participated in the observation study. Forty-six families participated in the first wave of the prospective questionnaire study (mother, father and child ($N = 18$), mother and child: ($N = 10$), father and child: ($N = 1$), mother and father: ($N = 7$), only mother: ($N = 6$), only father: ($N = 1$), mother, mother and child ($N = 1$), mother, grandmother and child ($N = 1$), mother and grandmother ($N = 1$)). In the second wave of the prospective questionnaire study, 40 families participated (mother, father and child ($N = 12$), mother and child: ($N = 11$), father and child: ($N = 1$), mother and father: ($N = 8$), only mother: ($N = 5$), only father: ($N = 1$), mother, mother and child ($N = 1$), mother and grandmother ($N=1$)). Six families withdrew from the study after wave 1, and out of 3 families, one family member withdrew (2 fathers, 1 mother, 1 child). Out of 2 families, one family member entered the study in wave 2 (1 father, 1 child). Thirty-nine families participated in the third wave (mother, father and child ($N = 15$), mother and child: ($N = 7$), father and child: ($N = 1$), mother and father: ($N=7$), only mother: ($N=5$), only father: ($N = 2$), mother, mother and child ($N = 1$), mother and grandmother ($N=1$)). Two families withdrew after wave 2, and out of 3 families, one family member withdrew from the study (1 mother, 2 children). One family (father, mother and child) reentered the study in the third wave. Out of 2 families, one family member reentered the study in wave 3 (2 fathers). In the final wave of the prospective questionnaire study, 38 families participated (mother, father and child ($N = 15$), mother and child: ($N = 8$), father and child: ($N = 1$), mother and father: ($N = 7$), only mother: ($N = 4$), only father: ($N = 1$), mother, mother and child ($N = 1$), mother and grandmother ($N = 1$)). One family withdrew after wave 3 (father). Out of one family, 1 family member reentered the study in wave 4 (1 child).

Figure 2. Flow chart of recruitment during phase 2





Recruitment phase 3: Observation Study (C)

The initial idea for phase 3 was to recruit additional participants for the prospective questionnaire study until 200 families agreed to participate (see previous version of the IRRiCD protocol). This plan was based upon the assumption that phase 2 would have finished before the deadline of inclusion in the prospective study (i.e. December 2017), when least 40 participants had participated in the observation study.

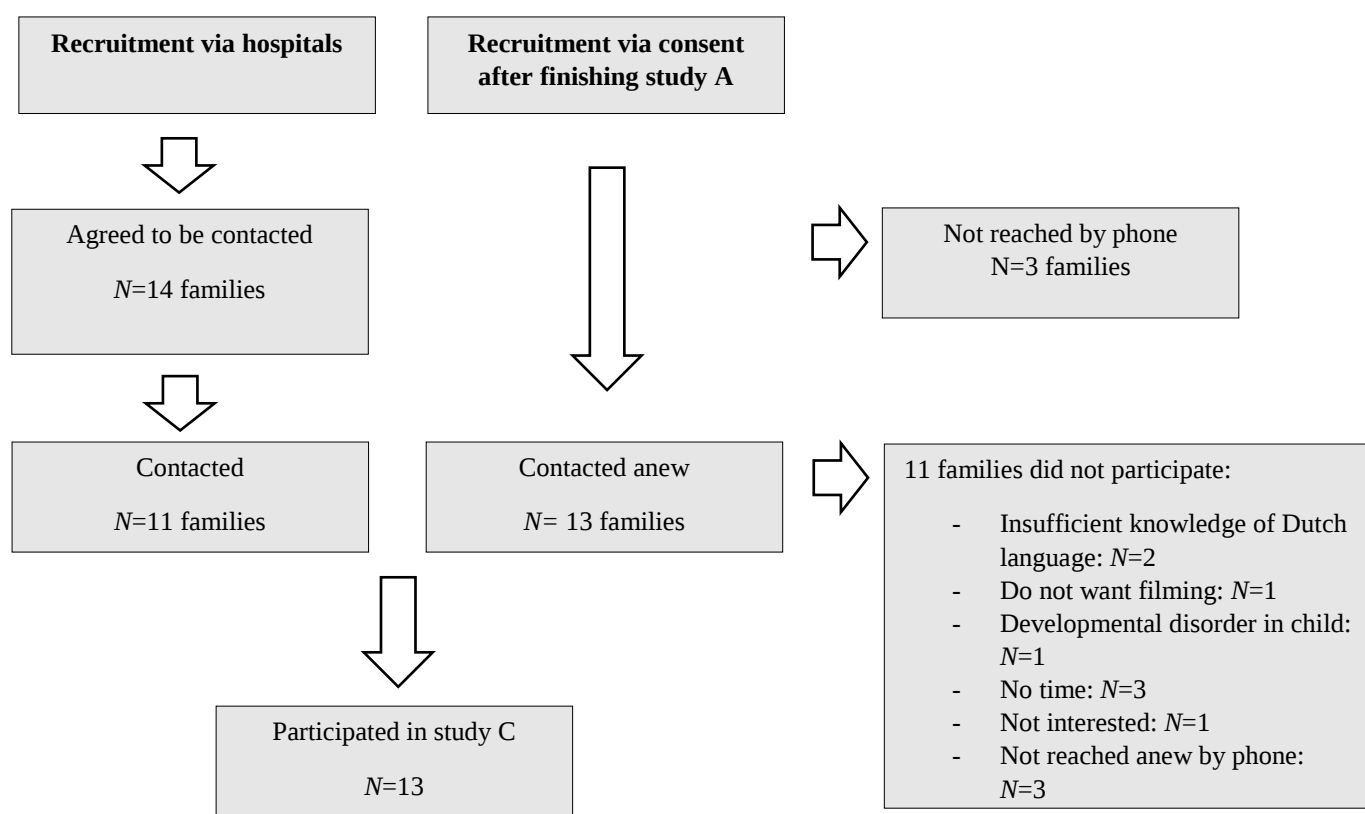
However, it was harder and took more time than expected to recruit participants. Phase 2 was ended in December 2017, in order to make it possible for all participants to end the forth wave of the prospective questionnaire study within the planned timeframe of the project. As only 20 families participated in the observation study by the end of phase 2, we decided to focus in the third phase upon the recruitment of additional participants for the observation study (C). Additional participants for the observation study were recruited in two ways.

First, pediatricians of three hospitals (University hospital Ghent, Sint-Jan Hospital in Bruges, and Queen Paola Child Hospital Antwerp) were asked to inform all families who met the inclusion criteria, had not yet been informed on the IRRiCD project, and had a routine clinic visit between January 2018 and December 2018, about the observation study. Families who agree to be contacted ($N = 14$) were phoned by a research assistant and asked if they were willing to participate in the observation study.

Second, families who participated in the first recruitment phase of the IRRiCD project, had finished the forth wave of the prospective questionnaire study, and had consented to be contacted for further research, were contacted again when the child was still under 13 years of age ($N = 13$).

Three families could not be reached by phone. Out of the 24 families that were contacted in phase 3, 13 families participated in the observation study. Eleven families withdrew participation for various reasons.

Figure 3. Flow chart of recruitment during phase 3



3. Recruitment: Comparison group

For the recruitment of a control group at the first wave of the questionnaire study (study A) a collaboration was set up with Prof. dr. T. Vervoort (UGent). A sample of parents and children from the general population was recruited through schools.

Recruitment procedure: Research assistants contacted 33 schools, of which 9 (5 primary and 4 secondary schools) agreed upon participation.

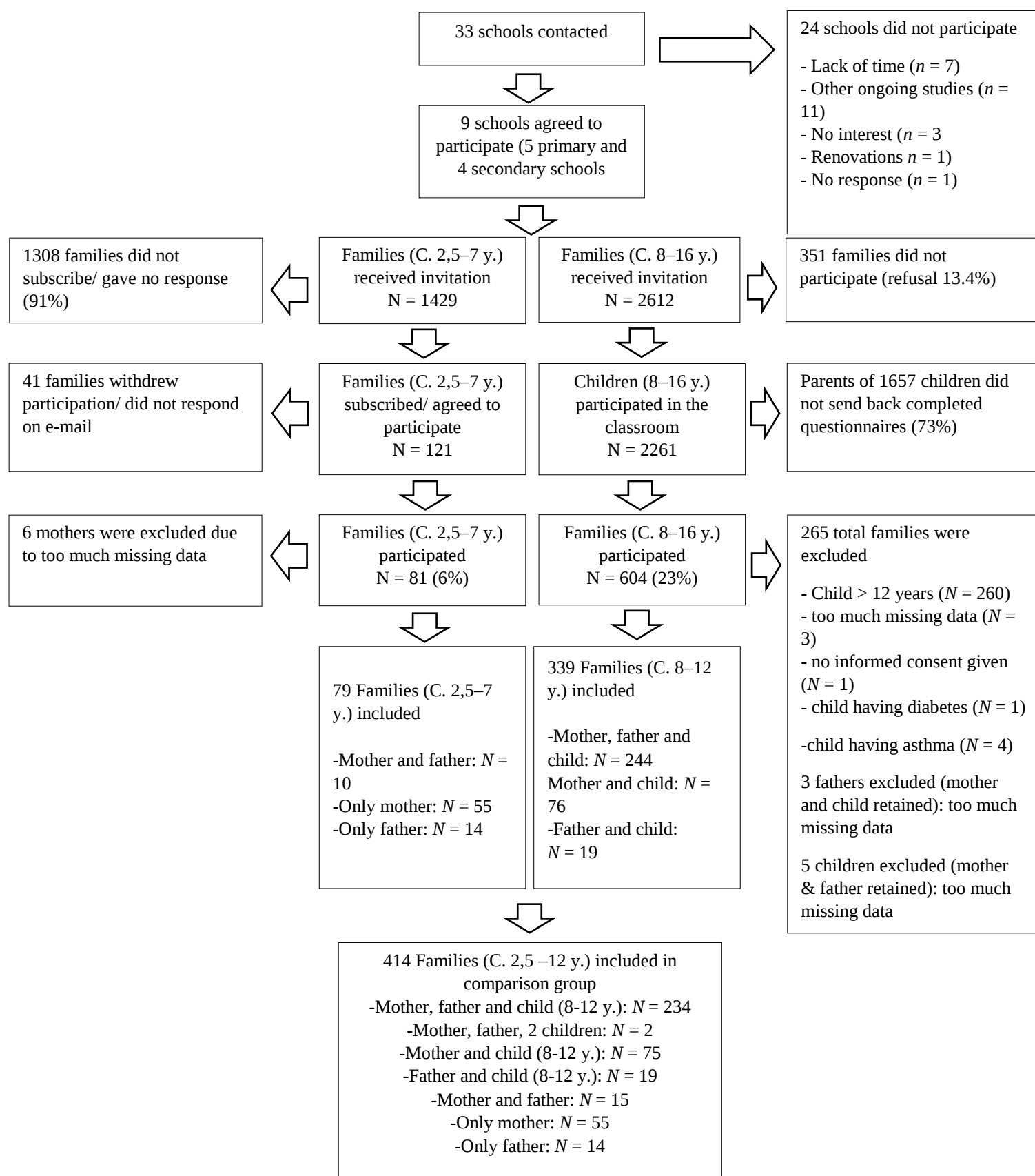
In the youngest age group (2,5 - 7 years) all children ($N = 1429$) from 1st kindergarten to 2nd grade received an invitation letter for their parents, with information about the study. Parents were asked to return the letter to school or subscribe on the website if they were interested to take part. Parents of 121 children subscribed (online: 24, through school: 97) and received an e-mail containing a web link to the questionnaires and a personal code. In total 89 parents (10 mother-father dyads, 54 mothers only, 14 fathers only) of 81 children between 2,5 and 7 years old completed the questionnaires. In 2 families, mother and father reported on a different child (siblings).

In the oldest age group (8 – 16 years) all children ($N = 2612$) from 3th to 9th grade and their parents were invited to take part in the study. They received an information letter, accompanied by a passive informed consent for participation of the child. In total 2261 children completed the questionnaires under supervision in the classroom during regular school hours, and received paper versions of the questionnaires for their parents. Parents (mother and/or father) of 604 children returned completed questionnaires to the researchers, by mail. Later on, 265 total families and 3 fathers were excluded (not meeting inclusion criteria or too much missing data), resulting in a sample of 339 families (mother, father and child ($N = 239$), mother and child: ($N = 76$), father and child: ($N = 19$), mother and father ($N = 5$)).

This resulted in a total sample of 418 families.

Inclusion criteria comparison group: (1) children aged between 2 and 12 years, (2) child (8-12 years) and parent having sufficient knowledge of the Dutch language and (3) child (8-12 years) and parent having sufficient mental abilities to complete the questionnaires. Children with type 1 Diabetes and other chronic diseases were excluded.

Figure 4. Flow chart of recruitment: comparison group



4. Procedure

The procedure was different depending on the phase in which the participants were recruited and the studies they agreed to take part in.

Phase 1:

- Study A:
 - Parents and child (8-12 years): 4 waves of questionnaire administration, each 6 months apart.
- Study A and B:
 - Parents and child (8-12 years): 4 waves of questionnaire administration, each 6 months apart.
 - Parents: diary assessment, immediately following wave 1.

Phase 2:

- Study A:
 - Parents and child (8-12 years): 4 waves of questionnaire administration, each 6 months apart.
- Study A and C:
 - Parents and child (8-12 years): 4 waves of questionnaire administration, each 6 months apart.
 - Parents and child (2-12 years): home observation of mealtime situation in between wave 1 and 2 or wave 2 and 3.

Phase 3:

- Study C:
 - Parents and child (2-12 years): home observation of mealtime situation in between wave 1 and 2 or wave 2 and 3.

4.1. Study A: Prospective questionnaire study

Clinical sample: In study A, parents of children with T1D (2-12 years) filled out several questionnaires at home, online (via Lime Survey Software), on 4 measurement times, each 6 months apart. The children with T1D themselves (8-12 years) were also asked to complete a limited set of questionnaires, each wave. At wave 1, children filled out the questionnaires under supervision of a researcher, during a meeting in the hospital following a routine consultation with their pediatrician. At wave 2-4 children completed the questionnaires online (via Lime Survey Software), at home. As an objective measure of child's glycemic control, glycosylated hemoglobin (HbA1c), measured before and after each questionnaire administration, was extracted from the child's medical record.

Child questionnaires (8-12 years) – Total number of items: 99 ($\pm$ 20 minutes):

- Pediatric Quality of life Diabetes Module (PedsQL; Varni et al., 2003) - 32 items
- Generic Pediatric Quality of Life (PedsQL; Varni et al., 2003) – 23 items
- Parenting Dimensions questionnaire (for mother and father):
 - Autonomy support: 7 items from the Autonomy Support Scale from the Perceptions of Parents Scale (POPS; Grolnick, Ryan, & Deci, 1991)
 - Psychological control: 8-item Psychological Control Scale – Youth Self-Report (PCS-YSR; Barber, 1996)
 - Responsivity: 7 items from the Child Report of Parent Behavior Inventory (CRPBI; Schludermann & Schludermann, 1970)

Parent questionnaires. The same variables were measured at each wave, apart from the Mindfulness questionnaires, who were only administered at waves 1 and 3 - Total number of items: 356/358 ($\pm$ 50 minutes):

- Socio-demographic and disease specific information (Age, gender, SES, disease duration, ...) – 33 items
- PROMIS Anxiety and Depression (PROMIS; Terwee et al., 2014) – 12 items
- Perceived Stress Scale (PSS; Cohen, Kamarck, & Mermelstein, 1983) – 10 items

- Pediatric Inventory for Parents (PIP; Streisand, Braniecki, Tercyak, & Kazak, 2001) – 42 items
- Hypoglycemic Fear Survey Parents of Young Children (HFS-P-YC; Patton et al., 2008) - 26 items
- Parent version of the Brief Illness Perception Questionnaire (IPQ; Broadbent, Petrie, Main, & Weinman, 2006) – 10 items
- Pediatric Quality of life Diabetes Module (PedsQL; Varni et al., 2003) – 32 items
- Generic Pediatric Quality of Life (PedsQL; Varni et al., 2003) – 21 / 23 items
- Diabetes Independence Survey – Parent version (DIS; Wysocki et al., 1996) – 38 items
- Strengths and Difficulties Questionnaire (SDQ; van Widenfelt, Goedhart, Treffers, & Goodman, 2003) – 25 items
- Parental Overprotection Measure (OP; Clarke, Cooper, & Creswell, 2013) – 19 items
- Parenting Dimensions questionnaire:
 - Autonomy support: 7 items from the Autonomy Support Scale from the Perceptions of Parents Scale (POPS; Grolnick, Ryan, & Deci, 1991)
 - Psychological control: 8-item Psychological Control Scale – Youth Self-Report (PCS-YSR; Barber, 1996)
 - Responsivity: 7 items from the Child Report of Parent Behavior Inventory (CRPBI; Schludermann & Schludermann, 1970)
- Kentucky Inventory of Mindfulness (KIMS-E; Raes, Dewulf, Van Heeringen, & Williams, 2009) – 46 items
- Mindful Attention Awareness Scale (MAAS; Brown & Ryan, 2003) – 15 items
- Interpersonal Mindfulness in Parenting Scale (IM-P; de Bruin et al., 2014) – 31 items

Comparison sample: In study A, a sample of parents and children (8-12 years) from the general population completed a set of non-diabetes specific questionnaires at wave 1. Parents of the youngest children (2,5-7 years) filled out the questionnaires online (via Lime Survey Software), at home. Children (8-12 years) completed the questionnaires under supervision in the classroom during regular school hours. Parents of the oldest children (8-12 years) completed paper and pencil versions of the questionnaires at home and returned them to the researchers by mail.

Child questionnaires (8-12 years) - Total number of items: 207 ($\pm$ 40 minutes):

- Generic Pediatric Quality of Life (PedsQL; Varni et al., 2003) – 23 items
- Parenting Dimensions questionnaire (for mother and father):
 - Autonomy support: 7 items from the Autonomy Support Scale from the Perceptions of Parents Scale (POPS; Grolnick, Ryan, & Deci, 1991)
 - Psychological control: 8-item Psychological Control Scale – Youth Self-Report (PCS-YSR; Barber, 1996)
 - Responsivity: 7 items from the Child Report of Parent Behavior Inventory (CRPBI; Schludermann & Schludermann, 1970)
- Questionnaires, not related to the current study: 140 items

Parent questionnaires - Total number of items: child <8y.: 146/148 ($\pm$ 20 minutes) ; child $\geq$ 8y.: 295/297 ($\pm$ 45 minutes):

- Socio-demographic and disease specific information (Age, gender, SES, disease duration, ...) – 22 items
- PROMIS Anxiety and Depression (PROMIS; Terwee et al., 2014) – 12 items
- Perceived Stress Scale (PSS; Cohen, Kamarck, & Mermelstein, 1983) – 10 items
- Generic Pediatric Quality of Life (PedsQL; Varni et al., 2003) – 21/ 23 items
- Strengths and Difficulties Questionnaire (SDQ; van Widenfelt, Goedhart, Treffers, & Goodman, 2003) – 25 items
- Parental Overprotection Measure (OP; Clarke, Cooper, & Creswell, 2013) – 19 items
- Parenting Dimensions questionnaire:
 - Autonomy support: 7 items from the Autonomy Support Scale from the Perceptions of Parents Scale (POPS; Grolnick, Ryan, & Deci, 1991)

- Psychological control: 8-item Psychological Control Scale – Youth Self-Report (PCS-YSR; Barber, 1996)
- Responsivity: 7 items from the Child Report of Parent Behavior Inventory (CRPBI; Schludermann & Schludermann, 1970)
- Mindful Attention Awareness Scale (MAAS; Brown & Ryan, 2003) – 15 items
- Questionnaires, not related to the current study (only for parents of children ≥ 8 y.): 149 items

4.2. Study B: Diary study

In study B, parents of children with T1D (2-12 years) completed a diary, every evening, for 14 consecutive days. Diary administration started immediately after wave 1 of study A or, if applicable, after a school holiday. The diary took approximately 5 to 10 minutes each evening to complete. All parents were sent daily text messages at 7 PM as a reminder to complete the diary.

- General information:
 - Hours together with child (1 item)
 - General perception of the day (1 item)
 - Number of blood glucose checks (1 item)
- Parent:
 - Worries of hypoglycemia / hyperglycemia (4 items)
 - Experiential avoidance (1 item)
 - Positive and negative affect (9 items)
 - Hypoglycemia avoidance behavior (3 items)
 - General overprotective behavior (3 items)
 - Parenting behavior: Psychological control (3 items), Autonomy support (2 items) and Responsivity (2 items)
- Child:
 - Severity of diabetes symptoms (2 items)
 - Interference of diabetes in the day planning of the child (1 item)
 - Positive and negative affect (9 items)
 - Problem behavior: general (3 items) and diabetic specific (3 items)
 - (Authorized) self-care autonomy (1 item)

A part of the diary was only assessed when a difficult diabetes-related situation occurred that day (as rated on 2 items). If applicable, parents were asked to describe the most difficult diabetes-related situation (DDS) of that day and additional items were administered, assessing parental worries and behavior related to that situation.

- Parent:
 - Worries of hypoglycemia before DDS (1 item)
 - Positive and negative affect before and after DDS (2x 9 items)
 - General overprotective behavior during DDS (1 item)
 - Parenting behavior: Psychological control (3 items), Autonomy support (2 items) and Responsivity (1 item) during DDS
- Child;
 - Severity of diabetes symptoms before DDS (1 item)
 - Positive and negative affect before and after DDS (2x 9 items)
- General:
 - Ending of DDS (1 item)

4.3. Study C: Observational study

In study C, a home visit was scheduled, during which a mealtime situation was videotaped.

Before the home visit, parents completed an online set of questionnaires (via Lime Survey Software). Total number of items: 106 (± 15 minutes):

- Pediatric Inventory for Parents (PIP; Streisand, Braniecki, Tercyak, & Kazak, 2001) – 42 items
- Perceived Stress Scale (PSS; Cohen, Kamarck, & Mermelstein, 1983) – 10 items
- Illness intrusiveness (IIS-P; Nicole R. Andrews et al., 2009) – 39 items
- Mindful Attention Awareness Scale (MAAS; Brown & Ryan, 2003) – 15 items

During the home visit the researcher explained the aims and the course of the study. The researcher completed the socio-demographic information together with the parents, and parents completed the STAI (6 items). Two cameras were installed in the dining room, on a discrete place. The mealtime situation, including blood glucose monitoring and insulin administration was videotaped. The researcher took place in another room. The total home visit took about 1 hour.

At the end of the mealtime situation, parents were asked if the situation was typical or different from other days, both parents completed the STAI again (anxiety during mealtime), filled-out the worry questionnaire, and were asked to sign a contract concerning the use of the video material.

- State Scale of the Spielberger State-trait Anxiety Inventory Short-form (6 items) (Marteau & Bekker, 1992) (how do you feel right now) : after mealtime
- Parental Worries about hypoglycemia and hyperglycemia (4 diary items, based upon Hypoglycemia Fear Survey – Parents of Young Children (HFS-P-YC; Patton, Dolan, Henry, & Powers, 2008) (past 7 days) : after mealtime

All videos were coded, using the OKI-DO observation instrument (Nieuwesteeg et al., 2014). The OKI-DO instrument rates behavior on 10 different domains (4 parent domains, 4 child domains and 2 family domains). Parent(s) and child are rated on each domain, on a 5-point Likert scale. Higher scores reflect more of the behavior.

- Parent domains:
 - Emotional involvement
 - Limit setting
 - Respect for autonomy
 - Quality of instruction
 - Overprotection (scale developed for the current study)
- Family domains:
 - Emphasis on diabetes
 - Mealtime structure
- Child domains:
 - Negative behavior
 - Avoidance
 - Cooperative behavior
 - Child's response to injection

5. References

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