Appendix 3. Protocol search and assessment

To identify the protocol or any written information that can provide the required data, we have used the following approaches:
1) e-mail contact;
2) reference search (in the same article) of previous publication or a supplemental file that can be used for additional information;
3) any possible trial registration that appears in the paper (e.g., clinicaltrial.gov); and
4) a general search in the internet (Google) using the word “protocol”, the first author and relevant keywords from the title. For every e-mail that returned back, we have attempted to search the most recent e-mail address (Pubmed).

The Figure described the process of protocol identification.

Overall, 14 prepublication protocols were retrieved.

Of the 7 studies classified as *ITT trials,* Beasley 1996a[1] reports in the protocol one deviation contradicting the final publication; Porthouse [2], Prince [3]and Vulink [4]did not report any intention-to-treat approach in the protocol; only Dellinger [5], Kaiser [6]and von Minckwitz [7]were concordant in the intention-to-treat description.

Of the 5 studies classified as *mITT trials*, no information about intention-to-treat was provided in the corresponding protocols[8-12].

Of the 2 studies classified as *no ITT trials* no information about intention-to-treat was provided in the protocol[13, 14].

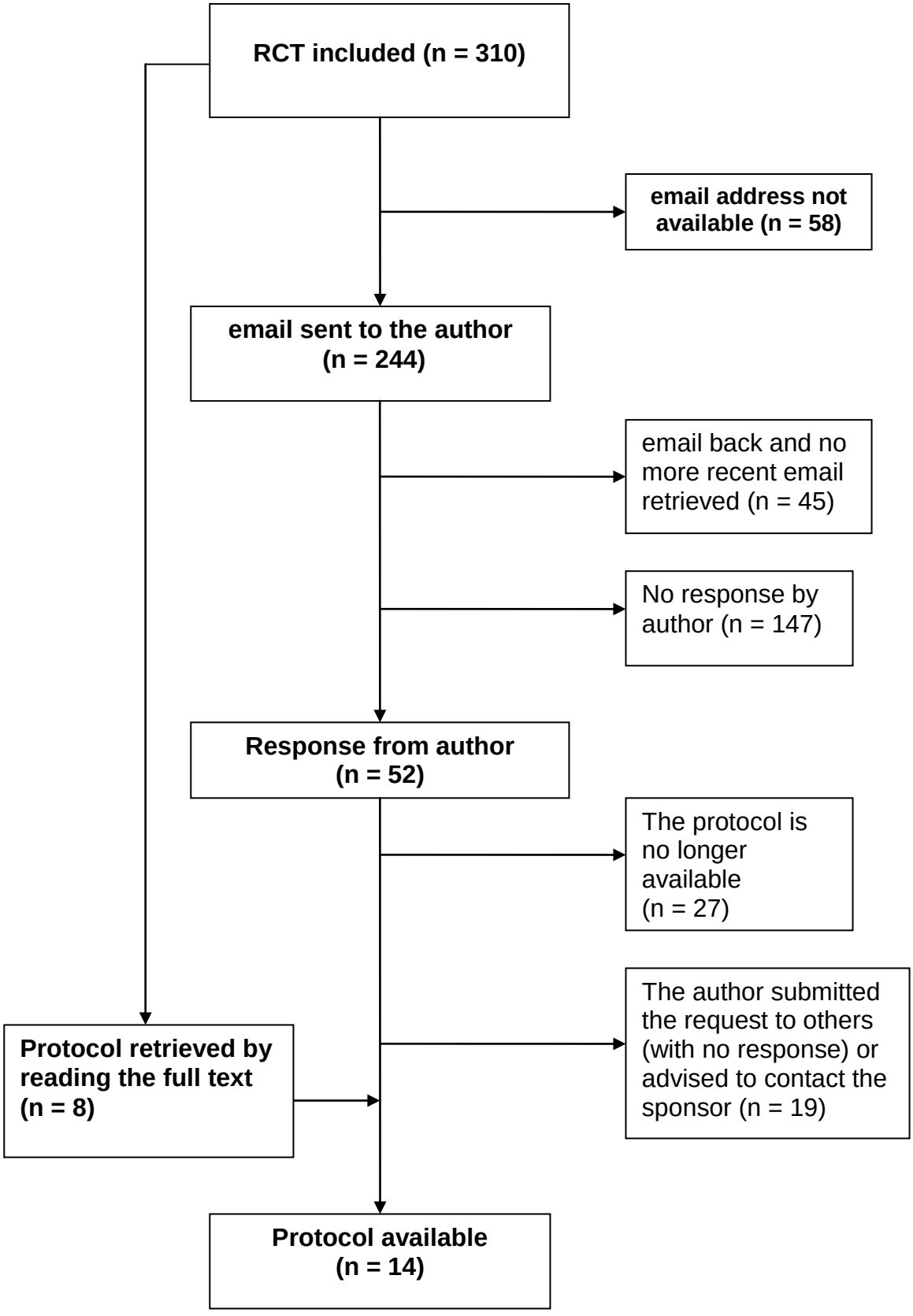
The following Table compares the intention-to-treat approach reported in the included studies and the corresponding prepublication protocols.

RCT	Pre-publication Protocol	Final study
Beasley 1996a	All randomized patients for which there is at least one post-baseline measurement will be included in the analyses in accordance with an "intent-to-treat" principle”. **(mITT)**	**ITT trial**: “All analysis was done on an intention-to-treat basis, meaning all patients were included in the groups to which they were randomly assigned, even when the patient did not strictly adhere to the protocol”.
Porthouse 2005	No information about ITT analysis. **(noITT)**	**ITT trial**: “Women who after randomisation were identified as having contraindications to calcium and vitamin D supplements were excluded from supplementation but were retained for follow-up and analysis on an intention to treat basis.”
Prince 2008	No information about ITT analysis **(noITT)**	**ITT trial**: “The main intention-to-treat analysis included all 302 subjects enrolled”.
Vulink 2009	No information about ITT analysis. **(noITT)**	**ITT trial**: “The primary outcome measure was the mean change from baseline to endpoint on the

		total score of the YBOCS in the intent-to-treat (ITT) population using the last observation carried forward (LOCF) analysis".
Dellinger 2007	"The ITT population will contain all subjects randomised to the trial. Subjects will be included in the analysis according to their randomised therapy irrespective of the therapy they actually received". **(ITT)**	**ITT trial**: "All analyses were based on all patients randomized into the study (intention-to-treat population)".
Kaiser 2000	"Intention-to-treat population for efficacy: the Intention-to-Treat population was defined as all randomised patients, regardless of the amount of study drug actually taken. This was the primary population for assessing efficacy. For the purposes of analysis, data for patients who did not take study medication as per the randomization schedule was included in the treatment group to which the patient was randomised". **(ITT)**	**ITT trial**: "All analyses were performed on an intention-to-treat basis"
von Minckwitz 2009	Efficacy Evaluation: "An intention to treat (ITT) analysis will be conducted for all patients. In addition, an analysis will be conducted among the eligible patients. Safety evaluation: "The primary safety analysis will be conducted on all patients who received at least one dose of study medication, i.e. the sample size will be the same as in the intent to treat analysis. Groups are defined by the actual received study medication. **(ITT)**	**ITT trial**: "The primary analysis was performed as an intent-to-treat analysis. All patients included in the intent-to-treat analysis were included in the safety analysis".
Bracco 2009	No information about ITT analysis. **(noITT)**	**mITT trial**: "The intent-to-treat population consisted of all subjects who received 1 dose of study treatment".
Di Leo 2008	No information about ITT analysis. **(noITT)**	**mITT trial**: "The primary population was the intent-to-treat (ITT) population, which was defined as all randomly assigned patients who received one dose of study medication. The safety population was defined as all intent-to-treat patients according to actual treatment received rather than randomly assigned treatment".
Kärkkäinen	No information about ITT analysis. **(noITT)**	**mITT trial**: "Data was analysed on a modified intention to treat (ITT) basis by retaining allocation to groups according to randomization and by including all subjects in whom we had endpoint information".

Veldt	No information about ITT analysis. **(noITT)**	**mITT trial**: “All 117 patients who received at least one dose of treatment were included in the intention to treat analysis”.
Pfizer Protocol # A0081100	No information about ITT analysis. **(noITT)**	**mITT trial**: “Full Analysis Set (FAS) included all randomized participants who received at least 1 dose of study medication, regardless of medication compliance”.
Forrest	No information about ITT analysis **(noITT)**	**No ITT trial**
Ng	No information about ITT analysis **(noITT)**	**No ITT trial**

Figure. Protocol search process



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