Author’s response to reviews

Title: Diabetes distress in Indonesian patients with type 2 diabetes: a comparison between primary and tertiary care

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Author’s response to reviews:

31st December 2018

Dear

BMC Health Services Research Editorial Office,

Thank you for giving us the opportunity to submit a revised version of our manuscript entitled: ‘Diabetes distress in Indonesian patients with type 2 diabetes: a comparison between primary and secondary care’ BHSR-D-18-01610.

In the following sections we have addressed in detail the points raised by the editor and reviewers and replied to each point in turn. We think we have addressed all suggestions and the manuscript has been substantially improved.

All the authors have reviewed and approved the final version of the revised manuscript being submitted. The manuscript is not currently being considered elsewhere. If accepted, it will not be
published elsewhere, including electronically, in the same form, in English or any other language, without the written consent of the copyright-holder.

We hope that the revised manuscript meets the high standards of your journal.

We thank you in advance for your consideration of our revised manuscript and look forward to your response.

Kind regards,

Bustanul Arifin,
Antoinette D.I. van Asselt,
Didik Setiawan,
Jarir At Thobari,
Maarten J. Postma, and
Qi Cao.

Editor comments

1. Overall

Some language and editing needed

We acknowledge the comment from the editor and reviewers and have followed your kind suggestion.

2. Abstract

a. Make clear if previous studies were in Indonesia or globally

We agree with the editor. In this revised manuscript, we have revised the sentence (Page 2, Abstract, Background, line 47), as follows:
Four previous studies in U.S have found that higher DD scores were associated with worse psychological outcomes, lower health-related quality of life (HRQoL) and increased risk of T2DM complications.

b. For your conclusion, could you make this more specific to health systems and link what your work means for a health systems response to diabetes.

We agree with the reviewers, in this revised manuscript, we have modified our conclusion (Page 2, Abstract, Conclusion, line 66-68), as follows:

This is the first study in Indonesia to compare DD scores within different health-care facilities. We recommend a regular DD assessment, possibly closely aligned with health-literacy partner programs, especially for T2DM patients in the primary care setting.

3. Key words

Please revise these

We acknowledge the comment from the editor. In this revised manuscript, we have modified our key words (Page 2, line 69, Key words), as follows:

Diabetes distress, Indonesia, Primary care, Secondary care.

4. Introduction

a. Make clear if previous studies were in Indonesia or globally

We agree with the editor. In this revised manuscript we put the paragraph in the discussion and (the reviewer’s suggestion) have revised the sentence (Page 17, Discussion, paragraph 7, line 360), as follows:

Four previous studies in U.S have found that indeed higher DD scores, due to higher levels of distress, were associated with worse psychological outcomes, poor self-care, higher levels of haemoglobin A1c (HbA1c), lower health-related quality of life (HRQoL) and increased T2DM complications.
b. I would put the text from p. 4 lines 4-25 in the discussion.

We acknowledge the reviewer’s suggestion. In this revised manuscript, we have put the text in the Discussion (Page 17-18, paragraph 6-7, line 349-366), as follows:

Health services for Indonesian T2DM outpatients are managed in a tiered system, where patients receive initial care in a primary care setting; notably, in a puskesmas/public healthcare centre (PHC) or family doctor/general practitioner (GP) office. Patients can only receive advice from a consulting resident of internal medicine in secondary care in an emergency situation or when indicated by certain clinical symptoms [10]. Indonesians living with T2DM generally visit a health facility after their health condition has deteriorated due to T2DM complications [25]. The most common complications, indicated in a recent study were neuropathy and retinopathy complications [26].

People living with T2DM require a lifetime daily self-management plan [27]. The changes in their daily lifestyle and the disease may have a negative impact on their psychological state and may contribute to DD. DD refers to the fear of risk of T2DM complications, lack of accessibility to high-quality healthcare facilities, worries about self-management therapy and the perception of lacking emotional support from family and colleagues [4,6]. Four previous studies in U.S have found that indeed higher DD scores, due to higher levels of distress, were associated with worse psychological outcomes, poor self-care, higher levels of haemoglobin A1c (HbA1c), lower health-related quality of life (HRQoL) and increased T2DM complications [4,6,7,28]. Furthermore, periodic DD assessments are important to facilitate early detection of DD and subsequent potential prevention of more severe psychological disorders; notably, T2DM patients with higher DD scores have been found to have an increased risk of mortality [29]. Regular DD assessment has been recommended by the IDF since 2012 [30].

c. More is needed in your Introduction on the concept of DD and why this is important

In this revised manuscript, we have revised the Introduction. We have added a new paragraph (Page 3, Introduction, paragraph 2, line 79-88), as follows:

Introduction

Diabetes distress (DD) is a psychological condition which overlaps with anxiety, stress and depression [3]. In 2005, Polonsky et al published an assessment of psychological distress in diabetes patients in three cities in the U.S (San Diego, Boston, and Honolulu) [4]. Based on that research, Polonsky et al have developed the DD instrument labelled DDS (diabetes distress
scale), focusing on assessing DD in four domains: physician distress, emotional burden, regimen distress, and interpersonal distress [5]. In total, 28 items are covered in these 4 domains. In 2012, Fisher et al. have conducted further research to evaluate the association of the 28 DDS items with the clinical condition of their participants [6]. Based on the associations, the latest version of DDS could be reduced to only 17 items [4,6]. DD assessment is highly recommended because it complements other T2DM assessments, enabling a more comprehensive approach both clinically as well as psychologically [5,7].

5. Methods

Well described

Thank you very much.

6. Results

a. Table 1. What do the FBG and Postprandial glucose measures represent? Averages? What do the “N” s represent?

FBG and Postprandial glucose measures represent the biological measurement of blood glucose level. They are now reported as number of participants scoring below or above a certain level.

N represent number of participants reporting below or above the cut-off point

In this revised manuscript, we have re-organized our Table, as follows:

Table 1 (Page 11-12): Participants’ characteristics according to the different DD categories.

Table 2 (Page 13): Scores of diabetes distress for the participants in primary care compared to those treated in secondary care.

Table 3 (Page 13-14): Results of the ordinal regression models (n = 632).

b. The factors explaining differences in DD need much more detail and explanation. These are not clear as they stand and is really level of care that is important or more the socio-demographic factors. Overall your Results Section needs to be much more detailed than it currently is

In this revised manuscript we have added one additional Table to cover this level of detail (Table 1, Page 11-12, line 245-260), as follows:
Participants’ characteristics according to the different DD categories

Percentages of participants reporting moderate and high DD were higher in primary than in secondary care. Also in primary care, the percentage of moderate and high DD was higher in female participants compared to male participants, but this was not the case in secondary care. The group of participants with education levels up to senior high school reported higher DD than those with university degrees. Regarding type of work, housewives reported the highest DD. Groups of participants with dependence on caregivers reported higher DD scores than those who came alone, both in primary and secondary care.

Based on clinical condition, higher DD scores were reported by those who were undergoing a T2DM therapy. Therapy complexity (insulin mono or combinations) might explain higher DD scores, as well as worries about pharmacological treatment in general and adherence distress. In general, the results of our analysis showed that the more T2DM complications exist the higher DD is reported. Yet, in primary care there were 33% of participants without T2DM complications who still reported moderate DD and 6% even higher DD. Table 1 presents participants’ characteristics in primary and secondary care settings according to the different DD categories.

Table 1. Participants’ characteristics according to the different DD categories

<table>
<thead>
<tr>
<th>Variables</th>
<th>Primary Care</th>
<th>Secondary Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>DD categories</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Little or no DD</td>
<td>(a mean item score &lt;2)</td>
<td></td>
</tr>
<tr>
<td>Moderate DD</td>
<td>(a mean item score between 2.0-2.9)</td>
<td></td>
</tr>
</tbody>
</table>
High DD
(a mean DD score ≥3)

Primary  Secondary  Primary
n (%)  Secondary  
n (%)  Primary  
n (%)  Secondary  
n (%)  Primary  
n (%)  

Total 632 (100) 108 (32) 524 (26) 65 (60) 425 (81) 32 (30) 81 (15) 11 (10) 18 (4)

Socio-demographic characteristics

Sex
Male 265 (42) 35 (13) 230 (87) 26 (74) 182 (79) 6 (17) 38 (17) 3 (9) 10 (4)
Female 367 (58) 73 (20) 294 (80) 39 (53) 243 (82) 26 (36) 43 (15) 8 (11) 8 (3)

Age
Productive age (<56 years) 158 (25) 20 (13) 138 (87) 12 (60) 103 (75) 5 (25) 29 (21) 3 (15) 6 (4)
Retired age (>56 years) 474 (75) 88 (19) 386 (81) 53 (60) 322 (83) 27 (31) 52 (14) 8 (9) 12 (3)

Education
Up to senior high school 481 (76) 95 (20) 386 (80) 56 (59) 317 (82) 29 (30) 52 (14) 10 (11) 17 (4)
University degree 151 (24) 13 (9) 138 (91) 9 (69) 108 (78) 3 (23) 29 (21) 1 (8) 1 (1)
### Occupation

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
<th>Median</th>
<th>Quartile 1</th>
<th>Quartile 2</th>
<th>Quartile 3</th>
<th>Quartile 4</th>
<th>Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active employment</td>
<td>174</td>
<td>11</td>
<td>63</td>
<td>76</td>
<td>36</td>
<td>20</td>
<td>64</td>
</tr>
<tr>
<td>Unemployed/Retired</td>
<td>222</td>
<td>43</td>
<td>81</td>
<td>70</td>
<td>83</td>
<td>21</td>
<td>19</td>
</tr>
<tr>
<td>Housewife</td>
<td>236</td>
<td>54</td>
<td>82</td>
<td>52</td>
<td>84</td>
<td>35</td>
<td>77</td>
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</tbody>
</table>

### Dependence on caregiver

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
<th>Median</th>
<th>Quartile 1</th>
<th>Quartile 2</th>
<th>Quartile 3</th>
<th>Quartile 4</th>
<th>Mean</th>
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</thead>
<tbody>
<tr>
<td>Yes</td>
<td>381</td>
<td>57</td>
<td>85</td>
<td>53</td>
<td>77</td>
<td>37</td>
<td>60</td>
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<tr>
<td>No</td>
<td>251</td>
<td>51</td>
<td>80</td>
<td>69</td>
<td>88</td>
<td>22</td>
<td>40</td>
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</tbody>
</table>

### Clinical condition

**T2DM duration**

<table>
<thead>
<tr>
<th>Duration</th>
<th>Count</th>
<th>Median</th>
<th>Quartile 1</th>
<th>Quartile 2</th>
<th>Quartile 3</th>
<th>Quartile 4</th>
<th>Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than five years</td>
<td>179</td>
<td>13</td>
<td>7</td>
<td>93</td>
<td>1</td>
<td>8</td>
<td>17</td>
</tr>
<tr>
<td>More than five years</td>
<td>164</td>
<td>18</td>
<td>11</td>
<td>89</td>
<td>11</td>
<td>5</td>
<td>17</td>
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</tbody>
</table>

### Therapy

<table>
<thead>
<tr>
<th>Type</th>
<th>Count</th>
<th>Median</th>
<th>Quartile 1</th>
<th>Quartile 2</th>
<th>Quartile 3</th>
<th>Quartile 4</th>
<th>Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>None (diet, herbal, exercise)</td>
<td>24</td>
<td>12</td>
<td>50</td>
<td>65</td>
<td>8</td>
<td>67</td>
<td>1</td>
</tr>
<tr>
<td>OAD (mono and combinations)</td>
<td>369</td>
<td>72</td>
<td>20</td>
<td>58</td>
<td>72</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>297</td>
<td>47</td>
<td>65</td>
<td>84</td>
<td>21</td>
<td>29</td>
<td>39</td>
<td>10</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Type</th>
<th>Count</th>
<th>Median</th>
<th>Quartile 1</th>
<th>Quartile 2</th>
<th>Quartile 3</th>
<th>Quartile 4</th>
<th>Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin (mono and combinations)</td>
<td>141</td>
<td>15</td>
<td>11</td>
<td>26</td>
<td>87</td>
<td>34</td>
<td>12</td>
</tr>
<tr>
<td>Insulin+OAD</td>
<td>98</td>
<td>9</td>
<td>9</td>
<td>12</td>
<td>9</td>
<td>2</td>
<td>11</td>
</tr>
</tbody>
</table>

### Types of complications
None 224 (36) 51 (23) 173 (77) 31 (61) 146 (84) 17 (33) 22 (13) 3 (6) 5 (3)
Microvascular 50 (8) 7 (14) 43 (86) 3 (42) 28 (65) 2 (29) 14 (33) 2 (29) 1 (2)
Macrovascular 268 (42) 42 (16) 226 (84) 26 (62) 183 (81) 10 (24) 32 (14) 6 (14) 11 (5)
Macro and microvascular 50 (8) 5 (10) 45 (90) 4 (80) 37 (82) 1 (20) 8 (18) 0 (0) 0 (0)
Comorbidities 40 (6) 3 (7) 37 (93) 1 (33) 31 (83) 2 (67) 5 (14) 0 (0) 1 (3)

Number of T2DM complications
1 complication 230 (36) 36 (17) 194 (83) 24 (67) 155 (80) 8 (22) 31 (16) 4 (11) 8 (4)
2 or more complications 138 (22) 18 (13) 120 (87) 9 (50) 93 (78) 5 (28) 23 (19) 4 (22) 4 (3)

Blood glucose level#
Fasting blood glucose
<126 mg/dL 103 (16) 3 (3) 100 (97) 1 (34) 85 (85) 1 (33) 14 (14) 1 (33) 1 (1)
>126 mg/dL 155 (25) 6 (4) 149 (96) 4 (66) 119 (80) 1 (17) 24 (16) 1 (17) 6 (4)
Post prandial blood glucose
<200 mg/dL 138 (22) 7 (5) 131 (95) 4 (57) 109 (83) 1 (14) 19 (15) 2 (29) 3 (2)
>200 mg/dL 112 (78) 9 (8) 103 (92) 1 (50) 83 (81) 1 (50) 16 (15) 0 (0) 4 (4)
Note: # : Number of participants reporting

7. Discussion
a. Levels of FBG and their link to DD – which way does this association work? Would it not be if you are more distressed you have a higher FBG?

In our study, we found that participants with higher level of FBG reported higher DD scores. This association is significant but the OR just being 1.01 (very weak).
In this revised manuscript, we stated this statement in Page 16, Discussion, paragraph 4, line 324-330, as follows:

This may be partly caused by the limited amount of factors included in this group (i.e., only T2DM duration and FBG level) and the weak but significant effect of the FBG level (OR=1.01) on DD score. Two more factors regarding clinical condition (type of therapy and postprandial glucose) were initially included in our regression model. However, these two factors were not included in the final models because with these variables included the models no longer met the proportional odds assumption, an important prerequisite to conducting the ordinal regression analysis in a more direct manner [18].

And we have compared our study with two previous studies (2-ways association) (Page 16, Discussion, paragraph 4, line 331-335), as follows:

A clinical trial in the U.S. reported that higher levels of blood glucose were associated with higher DD scores. Furthermore, in this U.S. study, it was reported that controlled blood glucose had a positive impact on mood, DD scores and HRQoL [21]. Besides, another study conducted on Hispanic and non-Hispanic patients in US as well reported that lower DD scores were associated with reductions in blood glucose levels [22].

b. I would like to see some discussion about the type of people that might be able to access secondary care versus primary care? Are there financial burdens, e.g. travel costs?

Generally, participants involved in this study are those who have easier access to health services. We assume, if data collection is done in several remote areas in Indonesia, transportation costs will be one of the main problems for them. As an illustration T2DM outpatients in one of the remote areas in Central Sulawesi may spend around USD$ 10.

In this revised manuscript, we have added an explanation related to Discussion (Page 19, paragraph 10, line 392-399), as follows:

It is important to highlight that the majority of the participants involved in this study were those who generally consistently followed the medication treatment, were compliant and regularly visited the health care facilities to get T2DM medicines. We assume this condition is reflected in our research results, that no participants are found with major DD. Further research should be
directed to complementarily analyse DD scores in non-compliant and less controlled T2DM patients. In addition to that, we assume if data collection is done in several remote areas in Indonesia, transportation costs will be one of the main problems for them. As an illustration T2DM outpatients in one of the remote areas (Mansalean village) in Central Sulawesi may spend around USD$10 reaching a health facility.

c. Line 41 you need a reference. More is needed on your Limitations.

We acknowledge the reviewer’s comment.

Page 17, Discussion, paragraph 4, line 328-330, as follows:

However, these two factors were not included in the final models because with these variables included the models no longer met the proportional odds assumption, an important prerequisite to conduct the ordinal regression analysis in a more direct manner [18].

And Page 1-819, Discussion, paragraph 9, line 387-391, as follows:

In addition, we also had difficulties in collecting T2DM duration and FBG levels, with only 40-50% of participants having the full evidence. Furthermore, the number of participants in secondary care was nearly five times higher than in primary care, as primary healthcare facilities seemed reluctant to participate in the study. More research in primary care facilities is therefore warranted.

d. It would be good to see DD specific discussion leading into lessons for the health system in general as well as how measuring DD is a tool to address challenges for the system and the patient. For example would you recommend DD being measured for each individual patient as part of the consultation?

In this revised manuscript we have added some implications and considerations for the general healthcare system (Page 19-20, Discussion, paragraph 12 and 13, line 406-442), as follows:

It can be implied from this research that serious consideration should be given to conducting T2DM and DD screening within the general context of Indonesian healthcare [33]. Screening is in particular warranted as the management of diabetes is continuously extending and improving, potentially with future consideration of DD being included. The risk of developing T2DM complications can be lowered by population-based prevention programmes (screening regularly
for T2DM in people at high risk). Obviously, the cost-effectiveness of the approach should be analyzed. Meanwhile, identified T2DM can be managed through several approaches, such as treatment and/or advice following early detection and diagnosis to prevent rapid complications of T2DM, providing easy access to integrative health facilities including psychological services, essential medicine and basic T2DM technologies [33]. Community support also contributes positively to DD, for example, aiding T2DM patients in accessing healthy food and sports facilities [34,35], illustrating the need for aligned health literacy programs for the patient and the environment, such as the partners and other family members. We therefore recommend that besides improving access to good health services for those with T2DM, primary care should be comprehensively strengthened in terms of the management of T2DM therapy. Furthermore, we recommend that the Indonesian government should provide psychological help and information in every healthcare facility to help T2DM patients with DD, and inclusive empowerment in the area of health literacy. Such psychological and information services could be embedded within a number of yet small-scale DM club activities (for example Prolanis BPJS). Further (preferably cost-effective) upscaling of these initiatives could be considered.

As one specific initiative, Prolanis concerns a chronic diseases management program organized by the BPJS that facilitates monthly visits between patients and a physician or a consulting resident of internal medicine. In these visits, the patient’s blood glucose is examined, followed by exercise and education about T2DM [36]. In Prolanis activities, doctors could play a role in providing T2DM education and information, while psychologists could provide psychological education to reduce DD. Another specific recommendation is that T2DM education should also be aimed at caregivers or family members because they are the ones who are able to monitor the developments of the therapies given to the T2DM patients, the disease course and the overall well-being. Such increasing awareness and education will empower health literacy of both the patients as well as the environment. It is likely that increasing awareness and educating Indonesians with T2DM not only about DM care but also about the reforms in the health insurance system and healthcare provision may be beneficial in reducing DD. Currently, DD screening has not become a priority in Indonesia even under the recommendation of the IDF [37] and American Diabetes Association [38] as being a global guideline for T2DM. If screening for DM is undertaken, DD should be one of the concerns of the Indonesian government. Additionally, we also recommend gender-specific approaches such as psychological consultations for female T2DM patients, especially housewives. Finally, educating T2DM outpatients about the reforms in the health insurance system and healthcare provision as well as engaging the family members in T2DM education may be beneficial to reduce DD.

8. Conclusion

“Our DD estimates can fruitfully be used in Indonesian healthcare policy making for
T2DM patients.” How? Please include this in your Discussion.

We agree with the editor. In this revised manuscript, we have added an explanation related to our conclusion (Page 23, Conclusion, line 406-442), as follows:

Regular DD assessment with good data management can be a reference for the government to determine the intervention type which is suitable for each level of health facility. For example, when there are more T2DM patients with a high DD score in the regimen distress domain in a health care facility, T2DM education and training should be improved.

Trisasi Lestari (Reviewer 1):

Overall, this is a simple and concise well-written manuscript for a study that has never been done in Indonesia. Sufficient information about the previous study findings is presented for readers to follow the present study rationale and procedures. The methods are generally appropriate, although some clarification should be provided. Specific comments follow.

Thank you very much for the compliment.

1. Page 5 Line 7. I expect that definition of primary/secondary care will refer to the facility. In the manuscript, it was described as patient who got treatment at the facility. How patient allocated to health facility also not fit with sub-heading. I recommend to create a separate new sub-heading describing study context and setting.

In this revised manuscript, we have modified this section (Page 5-10, Methods, line 105-238), as follows:

Participants and Methods

T2DM management in Indonesia

In Indonesia, the national health insurance is known as ‘BPJS (Badan Penyelenggara Jaminan Sosial)/ Social Security Administrative Agency’. Since January 1st, 2014, T2DM patients’ care
in Indonesia is managed by a referral system, where all T2DM patients will receive initial care in primary care (Puskesmas/ public healthcare center (PHC)) or family doctor [10]. Determination of the location of primary care is based on the location where the T2DM patients live, or by request of T2DM patients themselves [10]. At primary care level, the BPJS also has a chronic disease management program labelled Prolanis, which is an integrated and tiered T2DM patient service program aimed to improve the quality of life of T2DM patients in Indonesia [11]. The Prolanis program has existed since 2010, originally starting on the island of Java but having now spread to almost all regions of Indonesia [11]. Besides BPJS’s Prolanis, another community-based organization for T2DM patients exists, labelled Persadia (Indonesian Diabetes Association) [12]. Persadia consists of GPs, resident of internal medicine, nutritionists, T2DM patients, and their families, as well as others interested in diabetes issues. Persadia has branches throughout Indonesia, and in some areas of Java, has been actively conducting weekly educational activities to its members. Prolanis and Persadia both have the same goal. Therefore T2DM patients can follow the activities of both communities.

Research setting

Primary care

In our study, we defined primary care as the setting where T2DM outpatients are managed by a GP. Generally and additionally, every six months they have an opportunity to consult with a resident of internal medicine in a secondary care facility (see below for exact definition).

Secondary care

In secondary care, T2DM outpatients are treated in a hospital setting and monitored by a consulting resident of internal medicine. During the monitoring process, the resident of internal medicine plans the therapy according to guidelines, including the prescription of insulin for T2DM outpatients whose blood glucose remains uncontrolled with oral antidiabetic drugs (OADs) therapy. Insulin administration may continue for a certain period of time until the patient shows better clinical outcomes, for instance, his/her blood glucose is brought under control (for example, fasting blood glucose (FBG) ≤126 mg/dL) and afterwards, therapy may be reverted from insulin to OAD. Then, the consulting resident of internal medicine refers the patients back to a primary care facility for continuing OAD therapy. However, there are also some T2DM outpatients whose insulin therapy is not possible to be replaced with OAD, i.e. those who report OAD side effects or, based on clinical judgment, those in continued need of insulin [13]. For this group of patients, therapy continues in secondary care and they continue to be monitored by a resident of internal medicine. So far, insulin is only available in hospital pharmacies in secondary care and is not provided in primary care facilities in Indonesia. In areas with limited internal
medicine facilities, T2DM outpatients with insulin therapy can take routine examinations in a primary care facility and get the insulin at private pharmacies that collaborate with the BPJS. In practice, T2DM outpatients can directly visit the resident of internal medicine in a private clinic without a referral from a primary care facility, but then the service is not covered by health insurance.

Research context

Generally, health care facilities in primary and secondary care settings in Indonesia are public ones in which all health service procedures are managed by the government of Indonesia. In this research, all participants were covered with health insurance recommended by the government.

Study design and research sites

A cross-sectional study was conducted between February 2015 and April 2016. In primary care settings, participants were selected from a family doctor in Wonosari in Yogyakarta, a PHC in Surabaya (East Java) and a T2DM outpatients’ community in Surakarta (Central Java). Data collection was done every Friday and Saturday during a weekly patient education program. In secondary care settings, participants were selected from RSUD Kota Yogyakarta Hospital, PKU Muhammadiyah Hospital in Yogyakarta, Moewardi Hospital in Surakarta (Central Java) and BLUD RSUD Sekarwangi Hospital in Sukabumi (West Java). Most of the participants were interviewed in the waiting rooms of the hospitals while they were waiting for a consultation with a consulting resident of internal medicine. All the hospitals in this study were public teaching hospitals. During their handling of T2DM patients, all the consulting residents were under the supervision of an internist. The remaining participants were questioned in the waiting rooms of the hospitals’ pharmacies. The Medical Ethics Committee of Universitas Gadjah Mada (Yogyakarta, Indonesia) approved the study with document number KE/FK/1188/EC on November 12th, 2014 (the approval was amended on March 16th, 2015 due to the increased number of research sites).

Participants

We included outpatients with T2DM that were older than 18 years, read and signed a statement of willingness to participate, and were comfortable with filling out the questionnaire. For participants with limited reading ability or physical limitations, informed consent was given orally by the caregiver (spouses or children). As no information on duration of T2DM was available, this did not impact the inclusion.
Instrument

We used the Diabetes Distress Scale questionnaire in Bahasa Indonesia (DDS17 Bahasa Indonesia) [14] to measure the DD score. This instrument has been through a translation process, revision and validation into Indonesian language [14]. DDS17 Bahasa Indonesia consists of 17 items which are divided into four domains. First, three items are specified in the interpersonal distress domain concerning items on support from family members and colleagues of T2DM outpatients. Second, five items specify the emotional burden domain with regard to the concerns and fears of T2DM outpatients concerning complications. Third, four items in the physician distress domain describe opinions of T2DM outpatients concerning the knowledge and attitude of and the care provided by the treating physician. The last five items specified in the regimen distress domain measure difficulties of T2DM outpatients concerning the management of T2DM therapies (including motivation) and issues in self-confidence or stress, for example, caused by routine blood sugar checks. Each item consists of a scale ranging from 1 (not a problem) to 6 (a very serious problem) [4]. The resulting sum score of the 17 items would then range from 17, ‘not a problem’ to 102, ‘very serious problem’ [4].

Data collection procedure and data source

We collaborated with treating GPs and consulting residents of internal medicine to collect our data. The GPs and residents assisted us by providing participants with information about the research objectives, ethics and the importance of participating. This information helped participants to be more focused and comfortable and strengthened the feeling that the research was supported by the hospital staff. Participants were assisted by the researcher or the research assistant while filling out the questionnaire. All the research assistants involved in this research got training beforehand from the main researchers. In order to minimize bias, one of the main researchers was always with the research assistants during the data collection. Furthermore, the main researchers always discussed the data collection procedure before and after the data collection. During the data collection process, the same procedure was followed in the primary care and secondary care settings.

Socio-demographic characteristics such as age, sex, educational background, and occupation were collected using the participants’ identity cards and from self-reporting. In this study, the age of participants was classified into two categories: younger/productive age (18-56 years) or retirement age (>56 years). Furthermore, those aged 18-56 years who reported not currently having a job were defined as unemployed. Those who stated their main job is to take care of the household were classified as housewives, even when they were beyond the retirement age. Clinical condition such as the type of therapy, complications and comorbidities were obtained from the treating GPs and residents of internal medicine. Postprandial blood glucose, FBG and T2DM duration were collected from self-reporting. In this study, participants were defined as having comorbidities if they suffered from other major diseases besides diabetes, such as cancer.
or tuberculosis. Also, patients experiencing exclusive T2DM complications were identified as a separate group.

2. Page 5 line 24. It is not clear how many hospitals were involved and whether they are all teaching hospital. If all patient were supervised and managed by resident, what is the role of the specialist in the management of diabetic patient, and is this model also reflect the practice in non-teaching hospitals? It is also not clear whether management of DM described in the text referred to the national guideline of DM management in Indonesia or specific guideline from the hospital. Again, detail description of DM management in hospital is not really fit with the sub-heading.

We agree with you. In this revised manuscript we have added some explanation related to those issues (Page 5 and 7, Methods,), as follows:

T2DM management in Indonesia (Page 5, Methods, line 106-121)

(Page 7, Methods, Study design and research sites, line 159-160), as follows:

Study design and research sites

All the hospitals in this study were public teaching hospitals. During their handling of T2DM patients, all the consulting residents were under the supervision of an internist.

3. Page 6 line 4. What does "a consulting resident of internal medicine in private clinic" means?

We admit we made an error in the sentence. In this revised manuscript, we have corrected the sentence (Page 6, Participants and Methods, Research setting, Secondary care, line 143-145), as follows:

In practice, T2DM outpatients can directly visit the resident of internal medicine in a private clinic without a referral from a primary care facility, but then the service is not covered by health insurance.

4. Page 6 line 10. Instrument. Does the instrument has been tested before? Who, when, where the test was conducted, and what are the validity and reliability results?

DDS 17 Bahasa Indonesia has been tested by Arifin et al, from February to July 2015 in PKU Muhammadiyah Hospital in Yogyakarta, Moewardi Hospital in Solo, Central Java, and BLUD Sekarwangi in Sukabumi, West Java, RSUD Kota Yogyakarta Hospital, a family doctor in Wonosari, Yogyakarta, and in a public health center in Pakis, Surabaya, East Java.
In this revised manuscript, we have added a sentence about the validity of DDS17 Bahasa Indonesia (Page 7, Methods, Instrument, line 174-176), as follows:

We used the Diabetes Distress Scale questionnaire in Bahasa Indonesia (DDS17 Bahasa Indonesia) [14] to measure the DD score. This instrument has been through a translation process, revision and validation into Indonesian language [14].

5. Page 6 line 34. In a paper from Fisher et al., about the development of DD instrument, it was described that DD score was measured from the average of items score and not the sum of scores. Following the original guideline of the instrument will allow comparison with the original study.

In this revised manuscript we presented the DD scores from the average of items score (Page 13, line 265-267), as follow:

Table 2. Scores of diabetes distress of participants in primary care compared to those treated in secondary care

<table>
<thead>
<tr>
<th>Diabetes distress</th>
<th>Number of items</th>
<th>Primary care (n=108)</th>
<th>Median (IQR)</th>
<th>Secondary care (n=524)</th>
<th>Median (IQR)</th>
<th>Overall (n=632)</th>
<th>Median (IQR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total scores**</td>
<td>17</td>
<td>1.65 (1.24-2.41)</td>
<td>1.24 (1.06-1.76)</td>
<td>1.35 (1.06-2.06)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emotional burden**</td>
<td>5</td>
<td>1.60 (1.20-2.20)</td>
<td>1.00 (0.80-1.40)</td>
<td>1.00 (0.80-1.60)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physician distress**</td>
<td>4</td>
<td>1.75 (1.25-2.50)</td>
<td>1.25 (1.00-1.75)</td>
<td>1.25 (1.00-2.00)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regimen distress**</td>
<td>5</td>
<td>1.80 (1.20-2.60)</td>
<td>1.20 (1.00-1.80)</td>
<td>1.40 (1.00-2.20)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Interpersonal distress** 3 1.33 (1.00-2.00) 1.00 (1.00-1.67) 1.00 (1.00-2.00)

Note: A mean item score 2.0 – 2.9 should be considered ‘moderate distress,’ and a mean item score > 3.0 should be considered ‘high distress.’[5,7]

**P<0.01, IQR: inter-quartile range

6. Page 6 line 59. There is a potential selection bias for only recruiting patient who came to the weekly educational program, because i assume only patient who adhere/comply to treatment will come to the meeting, while those with lack of motivation or lack of access to health facilities will only visit the hospital for treatment or when they get really sick, as mentioned in the introduction.

Thank you very much for your comment. You are right ‘only patients who adhere/comply to the treatment will come to the meeting’. In this revised manuscript we have added a statement (Page 19, Discussion, Paragraph 10, Line 392-399), as follows:

It is important to highlight that the majority of the participants involved in this study were those who generally consistently followed the medication treatment, were compliant and regularly visited the health care facilities to get T2DM medicines. We assume this condition is reflected in our research results, that no participants are found with major DD. Further research should be directed to complementarily analyse DD scores in non-compliant and less controlled T2DM patients. In addition to that, we assume if data collection is done in several remote areas in Indonesia, transportation costs will be one of the main problems for them. As an illustration T2DM outpatients in one of the remote areas (Mansalean village) in Central Sulawesi may spend around USD$10 reaching a health facility.

7. Page 10 Table 1. Overall average total score of DD was only 23, with maximum score of 35. This is far from the maximum score of 102 and much closer to the based score of 17 which defined as not a problem. Looking at the average total score, i guess most respondent expressed lack of distress due to diabetes. Looking at the average score for each dimension, i guess majority of respondent have selected score 1 or 2 for each items and if i referred back to the original guideline, score 1 and 2 were defined as "not a problem". Therefore, describing that some patients have significantly higher distressed level can be misleading.

In this revised manuscript, we have re-organized our Table, as follows:

Table 1 (Page 11-12, line 259-260) : Participants’ characteristics according to the different DD categories.
Table 2 (Page 13, line 265-267): Scores of diabetes distress for the participants in primary care compared to those treated in secondary care.

We have also presented Table 2 at the average of DD scores (Page 13-14, line 282-286).

8. Page 11 Table 2. Despite its p-value, it is more important to describe its odds value. For example: odds for age is 0.97 and FBG 1.01 are both very close to 1 which shows no differences. Description in the text is misleading.

We agree with the reviewer. The effect size is only 1.01 indicating a very weak association between FBG and DD scores. In this revised manuscript we stated this statement in Page 16 (Discussion, paragraph 4, line 324-330), as follows:

This may be partly caused by the limited amount of factors included in this group (i.e., only T2DM duration and FBG level) and the weak but significant effect of the FBG level (OR=1.01) on DD score. Two more factors regarding clinical condition (type of therapy and postprandial glucose) were initially included in our regression model. However, these two factors were not included in the final models because with these variables included the models no longer met the proportional odds assumption, an important prerequisite to conducting the ordinal regression analysis in a more direct manner [18].

9. Page 12. Discussion. The questionnaire was mostly asked patient's long term experienced with Diabetes, and it is not clear how the transformation of health insurance system will influence the Distress Score. The author can highlight specific items of the questionnaire to support this hypothesis.

We acknowledge this comment. In this revised manuscript we have added some explanation related to this issue (Page 18, Discussion, paragraph 8, line 367-374), as follows:

In this study, during the data collection process, some of the elderly participants shared their experiences that since the transformation of the health insurance system (since 1 January, 2014), they were confused by the complicated procedure and bureaucracy of health care facilities. One of the impacts was a change in the physician that prescribed them the medical treatment. Often, they already felt comfortable with the previous doctor who served them and the change may have caused distress. Furthermore, as our data collection was conducted in a public area under-reporting of participants’ experience and psychological situation might have occurred due to reluctance of being critical to the authorities.

Specific item of the instrument: ‘Feeling that my doctor doesn’t know enough about diabetes and diabetes care’
10. The author should look back to the result and create conclusion based on the result. I think it is also interesting to show that majority of Diabetes patient in Indonesia does not experience major distressed. However, data collection methods should be highlighted as well, the fact that data collection was conducted in public area may lead to under-reporting of patient's experience and psychological situation.

In our opinion, the reviewer's comment supports her previous comment (Page 18, Discussion, paragraph 8, line 372-374), as follows:

Furthermore, as our data collection was conducted in a public area under-reporting of participants’ experience and psychological situation might have occurred due to reluctance of being critical to the authorities.

Bagoes Widjanarko (Reviewer 2):

1. In the introduction there is no explanation as to why this topic needs to be examined. The purpose and benefits of the results of research have not been clearly described. Researchers need to provide a more specific explanation about the background of health services at the research location to emphasize that this topic needs to be examined. Without this explanation, this research seems to only fulfill the researchers' wishes and is not based on scientific review.

We agree with the reviewer, in this revised manuscript, we have added a paragraph to facilitate this comment (Page 4, Introduction, last paragraph, line 96-104), as follows:

This research is important to be done in Indonesia because so far T2DM therapy is focused almost solely on the clinical aspects. It is important to be noted that recent studies have proven that psychological conditions of T2DM patients also highly influence levels of glycemic control and overall well-being [10]. Furthermore, this research can be used as a scientific base for the government of Indonesia in organizing T2DM program, especially in supporting the government program to strengthen the primary service in Indonesia.

2. In determining the participant, did researcher use the criteria for the length of treatment for both primary and secondary groups, given that based on the progression of the disease, the participant could move the level of service. Give an explanation of the procedure for selecting respondents in the method section.

In this research we do not have data about ‘length of treatment for both primary and secondary care’.

Related to the procedure of the participants selection, we have explained this (Page 7, Methods, Participants, line 170-171), as follows:

Participants
As no information on duration of T2DM was available, this did not impact the inclusion.

and an explanation of the procedure for selecting participants (Page 8, Methods, Data collection procedure and source, line 189-199), as follows:

Data collection procedure and data source

We collaborated with treating GPs and consulting residents of internal medicine to collect our data. The GPs and residents assisted us by providing participants with information about the research objectives, ethics and the importance of participating. This information helped participants to be more focused and comfortable and strengthened the feeling that the research was supported by the hospital staff. Participants were assisted by the researcher or the research assistant while filling out the questionnaire. In order to minimize bias, one of the main researchers was always with the research assistants during the data collection. Furthermore, the main researchers always discussed the data collection procedure, before and after the data collection. During the data collection process, the same procedure was followed in primary care and secondary care.

3. In the data collection procedure section the author states that the participant is given the impression that this research is supported by the hospital (page 7 line 22-30). Whether the author can guarantee the validity of the data, given that the respondent may feel reluctant with hospital personnel if they want to state certain things related to the service they receive.

In this research, hospital staff helped researchers in connecting with the participants, for example in assisting the consent form verbally. During the data collection, the participants reported their feeling that they were more comfortable in filling out the questionnaire during the research as long as the hospital supported and gave authorization to conduct a research. Moreover, some participants believed that the data they provided would be in safe hands because the hospital already gave approval.

In this revised manuscript, we also added this information in Page 18 (Discussion, paragraph 8, line 372-374), as follows:

Furthermore, as our data collection was conducted in the public area under-reporting of participants’ experience and psychological situation might have occurred due to reluctance of being critical to the authorities.
4. Is the same treatment done in the primary group?

Yes, the same procedure. In this revised manuscript, we stated this statement in Page 8 (Methods, Data collection and procedure and data source, paragraph 1, line 198-199), as follows:

During the data collection process, the same procedure was followed in primary care and secondary care.

5. To what extent are providers (GPs and residents) involved in determining respondents?

The treating physicians were involved in verbal informed consent for participants. But not in the selection. In this revised manuscript, we explained this issue in Page 8 (Methods, Data collection procedure and data source, line 199-199), as follows:

Data collection procedure and data source

We collaborated with treating GPs and consulting residents of internal medicine to collect our data. The GPs and residents assisted us by providing participants with information about the research objectives, ethics and the importance of participating. This information helped participants to be more focused and comfortable and strengthened the feeling that the research was supported by the hospital staff.

6. How do researchers provide assurance that there is no selection bias in this matter?

You are right. Thank you for reminding us. In this revised manuscript, we have added an explanation related to this issue (Page 18, Discussion, Paragraph 8, line 374-379), as follows:

Notably, above selection criteria on age and willingness to participate were applied. To avoid further selection bias, no other limitations on participation were applied. However, it is important to note that also the specific sites chosen and the type of outpatient that visits the sites did provide a specific selection. Furthermore, during the data collection, the researcher explained to the participants that any answer they provided would be kept private and confidential and an honest or subjective response would be helpful in developing T2DM services in Indonesia.

7. To what extent does the researcher and research assistant help participants in filling out the questionnaire (page 7 line 32)? Is this prepared by training to guarantee the standardization of the data collection process? The author needs to add an explanation

In this revised manuscript, we have added some explanations (Page 8, Methods, Data collection procedure and data source, paragraph 1, line 195-199), as follows:
All the research assistants involved in this research got training beforehand from the main researchers. In order to minimize bias effects within an overall as consistent approach as possible, one of the main researchers was always with the research assistants during the data collection. Furthermore, the main researchers always discussed the data collection procedure, before and after the process.

8. The author gives a statement of limitations of the study in the absence of HbA1c data (page 14 line 29). In what relation is this statement made? Is HbA1c expected as an indicator of therapeutic success or what? The author needs to provide an explanation of this.

We explained about the HbA1c in this research because previous global research has proven that levels of DD are associated with level of HbA1c. Unfortunately, during data collection process, we found it very difficult to find HbA1c data.

We mentioned the difficulties in our manuscript (Page 18-19, Discussion, paragraph 9, line 380-391), as follows:

Limitations of this study were that we were not able to measure the HbA1c of the participants. This is because not all health facilities are equipped with HbA1c examination facilities. For some T2DM outpatients with good economic circumstances, HbA1c examinations were conducted in private laboratories. Also, there is a difference in policies on HbA1c examinations between different health facilities. As an illustration, one particular PHC recommends only one HbA1c examination per year and on the condition that the T2DM outpatient is participating in activities organized by that particular PHC, whereas Health Minister regulation No.52 of 2016 [30] states that HbA1c examinations should be performed every 3 or 6 months. In addition, we also had difficulties in collecting T2DM duration and FBG levels, with only 40-50% of participants having the full evidence. Furthermore, the number of participants in secondary care was nearly five times higher than in primary care, as primary healthcare facilities seemed reluctant to participate in the study. More research in primary care facilities is therefore warranted.

9. "this is the first study to present DD score in Indonesia" (page 14 line 56), is this statement necessary as a basis for stating that the results of this study are representative for the island of Java?

You are right. This research was conducted in Java Island. However, we assume that Java Island can represent Indonesia as a whole country because more than 50% of the population reside in Java Island.

We stated in Page 19 (Discussion, paragraph 11, line 400-405), as follows:
This is the first study to present and compare DD scores in Indonesia, but limited in Java. Participants from our study were recruited from various healthcare providers such as family doctors, T2DM outpatient’ community, PHCs and hospitals so that we assume that the results of the study may provide an overall understanding of the state of DD in Indonesia. Moreover, although the Indonesian population is very heterogeneous, the Java population can be regarded as quite representative as 57% of all Indonesians reside in Java [31].