

## Effects of understanding wellbeing on psychological aspects and wound healing in patients with diabetic foot ulcer recurrence: a pilot randomised controlled trial

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There is an international consensus to the effect that optimising wellbeing is an appropriate approach to helping people living with wounds. However, implementation of this concept is difficult in practice. In the present study, a randomised controlled trial was conducted with the aim of evaluating the psychological aspects associated with diabetic foot ulcers (DFUs) by conducting an intervention focused on wellbeing. Sixty eligible participants were divided into two groups; both groups received local wound management, while the intervention group also received psychological treatment to enhance their understanding of wellbeing. The t-test and Mann–Whitney test were used to compare the two groups. In contrast to the authors' expectations, the findings indicated that patients with a DFU that received treatment on the understanding of wellbeing appeared to exhibit similar changes in psychological factors and acceleration of wound healing, compared to those who did not receive this intervention, except in the distress parameter at the second follow up.

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**T**he International Diabetic Federation (IDF) has reported that Indonesia is in the top 10 countries in the world in terms of the highest prevalence of diabetes mellitus (DM) (Shaw et al, 2010). The prevalence of DM in Indonesia has been increasing every year, and it has been predicted there will be 14.1 million patients by 2035 (Guariguata et al, 2014). In addition, the prevalence of diabetic foot ulceration (DFU) is in the range of 15–25% among DM patients (Boulton et al, 2005). In line with this prevalence, the DFU recurrence levels found in three studies were also high, at 42% (Bus et al, 2013), 57.5% (Dubský et al, 2013) and 37.9% (Ulbrecht et al, 2014).

Furthermore, by reviewing 19 compatible studies on incidence rates for ulcer recurrence, it is estimated that roughly 40% of patients have a recurrence within 1 year after ulcer healing, almost 60% within 3 years, and 65% within 5 years (Armstrong et al, 2017). In Indonesia, the DFU recurrence rate is considered high, at 57% (Arisandi et al, 2016). High recurrence rate would pose an undue medical or social burdens. Various approaches to reduce the complexity of care, and

minimise the risk of infection and the economic burden is designed by the health provider. However, recurrence is not due to factors such as the cause of the patient's behaviour, physical or psychological problems alone. Even a mixture of various factors contributes to the onset of recurrent ulcers.

Intervention combining various aspects, including physical, social, psychological and spiritual, is expected to encourage patients to achieve the goal of treatment (the healing of wounds). Considering this objective adopting the wellbeing concept as a basis for intervention to address the problems of patients with diabetic ulcer is a good intervention option. Positive wellbeing is expected to encourage self-efficacy of patients, reduce distress due to disease, improve quality of life and improve patient self-care.

### Wellbeing in relation to wound management

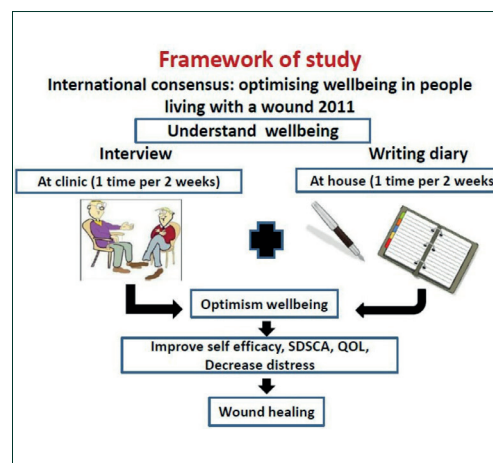
According to International Consensus (2012): "Wellbeing is a dynamic matrix of factors, including physical, social, psychological and

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**Table 1. Trigger question for interview understanding wellbeing.**

Number	Question
1	Has your wound improved or got worse? Please describe. If new, how did it happen?
2	Has your wound stopped you from doing things in the last week? If so, what?
3	What causes you the most disturbance/distress and when does this occur?
4	Do you have anyone to help you cope with your wound?
5	What would help to ease/improve your daily experience of living with a wound?

*Figure 1. Concept of psychological intervention according to International Consensus (2012).*



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spiritual. The concept of wellbeing is inherently individual, will vary over time, is influenced by culture and context, and is independent of wound type, duration or care setting. Within wound healing, optimising an individual's wellbeing will be the result of collaboration and interactions between clinicians, patients, their families and careers, the healthcare system and industry. The ultimate goals are to optimise wellbeing, improve or heal the wound, alleviate/manage symptoms and ensure all parties are fully engaged in this process."

Understanding wellbeing using discussion and reflection of one's own self with the writing of a diary will enhance the patient's realisation of optimising wellbeing. The feeling of optimism will increase confidence (self-efficacy) and further increase patient self care. Along with the confidence that positivity will reduce stress in disease conditions, there will ultimately be an increase in the quality of life in patients [Figure 1]. The effect of optimising wellbeing is an appropriate approach to helping people living with wounds. However, implementation of this concept is difficult in practice.

### The current study

Many programmes have been designed to address patients' wellbeing. However, current daily practice with regard to patient care in cases of DFU mainly focuses on diet, exercise, and

medication (Kurniawan et al, 2011). The physical aspects of a wound can be measured with various tools; however, the concept of wellbeing is more difficult to capture. Interventions that emphasise understanding wellbeing represent one conceptual approach that was developed by an expert working group for helping patients living with wounds. In addition, psychological aspects related to the promotion of wound healing and prevention of recurrence is rarely treated in Indonesia.

Therefore, this study aimed to evaluate psychological aspects by conducting an intervention consisting of understanding wellbeing. The primary outcomes evaluated were as follow: 1) self-efficacy (SE), 2) psychological distress (DDS), 3) summary of diabetes self-care activities (SDSCA), and 4) quality of life (QOL short form). The secondary outcome was wound closure or changes in DFU status, assessed by the diabetic foot ulcer assessment scale (DFUAS). Data were collected three times every 2 weeks during the 6-week study period.

## Methods

### Participants

There were 60 eligible participants with type 2 DFU who met the following criteria: age  $\geq 26$  years, level of haemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>)  $\geq 6.5\%$ , wound recurrence, and a wound grade of 1–5 according to the Wagner classification. The determined exclusion criteria were as follows: participants who had a wound above the ankle, DFU with systemic infection, white blood count (WBC) count  $>12,000 \mu\text{L}^{-1}$ , fever ( $>38.3^\circ\text{C}$ ), severe disease, congestive heart failure, chronic renal failure, and peripheral arterial disease. A recurrent ulcer was defined as any secondary ulcer, regardless of its location (Peters et al, 2007).

### Design

This pilot study took the form of a randomised controlled trial testing the 'Understanding Wellbeing' intervention relative to local wound management.

### Randomisation

The mechanism of a random allocation sequence was implemented by computer. The computer generated a list of random numbers, which was arranged sequentially and then placed in an envelope and sealed. When eligible participants arrived at the clinic, the envelope was taken from the container and opened. This study involved open blinding as both the researcher and participant knew the treatment that was administered.

**Table 2. Structured questions of diary.**

Number	Question
1	What has been the best thing that has happened to you today?
2	How would you describe how your wound has impacted on your day?
3	What has been the worst thing that has happened to you today?
4	Please take a photo of your dressing (or get someone else to take one if it is not accessible to you; a) has your dressing been changed today? Yes/no and b) If the dressing has been changed: how long did it take? Did someone change it for you?
5	If your dressing was changed today, how did you feel during the process?
6	How do you feel after the process?

**Table 3. Psychological characteristics.**

Characteristic	Intervention group (n=34)	Control group (n=26)	P
Self efficacy	18.3 (±3.0)	19.2 (±4.3)	0.323 <sup>a</sup>
Distress	40.1 (±4.3)	37.4 (±4.9)	0.028 <sup>a</sup>
Summary of diabetes self-care activities (SDSCA)	12.5 (5.5-22.5)	14.0 (5.5-36.5)	0.216 <sup>b</sup>
Quality of life	61.5 (±11.3)	61.3 (±9.8)	0.956 <sup>a</sup>

SDSCA, summary of diabetes self-care activity; <sup>a</sup> t independent test; <sup>b</sup> Mann Whitney test

**Table 4. Change over time in self-efficacy of two groups of patients with diabetic foot ulcers.**

Distress	Intervention (n=34)	Control group (n=26)	P
DISTRESS BL-F1	0.0(-11-7) (n=24)	-1.0(-13-8) (n=23)	0.855 <sup>b</sup>
DISTRESS F1-F2	0.5(-3-7) (n=20)	-1.5(-10-2) (n=16)	0.029 <sup>b</sup>
DISTRESS F2-F3	0.1(±4.2) (n=16)	1.2(±2.9) (n=13)	0.464 <sup>a</sup>
DISTRESS BL-F3	0.1(±4.7) (n=16)	-2.1(±5.3) (n=13)	0.252 <sup>a</sup>

<sup>a</sup> t independent test

**Table 5. Change over time in distress of two groups of patients with diabetic foot ulcers.**

Self-efficacy (SE)	Intervention (n=34)	Control group (n=26)	P
SE BL-F1	-1.0 (±3.4) (n=24)	-0.2 (±3.5) (n=23)	0.444 <sup>a</sup>
SE F1-F2	0.8 (±2.7) (n=20)	-0.8 (±2.1) (n=16)	0.080 <sup>a</sup>
SE F2-F3	-0.9 (±3.3) (n=16)	-0.1 (±1.9) (n=13)	0.418 <sup>a</sup>
SE BL-F3	-1.4 (±4.0) (n=16)	-1.5 (±3.5) (n=13)	0.987 <sup>a</sup>

<sup>a</sup> t independent test <sup>b</sup> Mann Whitney test

### Procedures

All eligible participants were given adequate information about the study. The explanation clarified the purpose of study, the time commitment required, the procedure, potential risks, cost, potential benefits, confidentiality, participants' rights and contact information. The research procedure was explained, and participants signed informed consent forms before assessment and treatment. During the study, participants have the right to withdraw from study without giving any explanation for

doing so. This study was approved by the ethics committee at Kanazawa University (No. 652-1).

### Intervention (understanding wellbeing)

Participants in the intervention group received local wound management along with Understanding Wellbeing treatment. The first treatment was performed in the clinic; during this treatment, the intervention group was interviewed, with the interviews including five trigger questions that would enhance the participants' understanding of wellbeing [Table 1] (International Consensus, 2012). In the second treatment, the patient wrote a diary at home to answer six structured questions. The completed diaries were collected when participants returned to the clinic. The interviews and diary writing were performed three times, once every 2 weeks, for each patient [Table 2] (International Consensus, 2012).

### Control (local wound management)

The control group received local wound management. Participants received wound treatment according to best practice at the wound care protocol Kitamura clinic: wound assessment, cleansing, debridement and wound dressing. Participants also received treatment advice, infection control and medicine according to the signs and symptoms they exhibited.

### Descriptive measures

Demographic data were taken at baseline which consist of gender, age, education, ethnic, marital status, family member, BMI, occupation, duration of diabetes, diet, oral hypoglycemia, insulin, blood sugar, HbA<sub>1c</sub>, neuropathy, medical history, ABI, and smoking. Table 3 provides psychological characteristics at baseline.

### Outcome measures

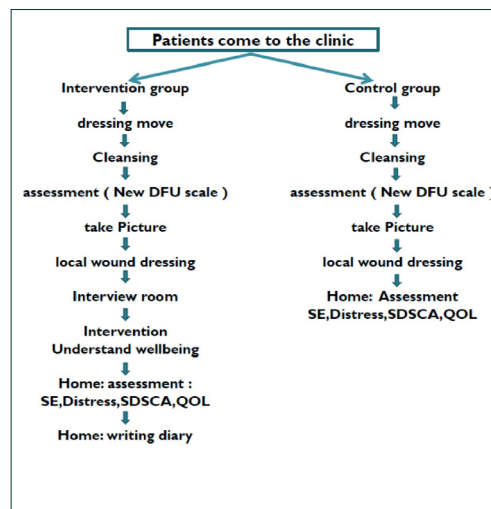
The primary outcomes evaluated were: 1) self-efficacy assessed by adapting an instrument (SE), consisting of seven items with a score range of 7–28 — a high score indicated good quality of life; 2) psychological distress assessed by adapting the psychological distress in diabetes (DDS), consisting of 12 item with a score range of 12–48 — a low score indicated distress; 3) self-care assessed by the summary of diabetes self-care activities (SDSCA) (Toobert et al, 2000), consisting of 11 items with a score range of 0–77; the items in this tool measure are diet, physical activity, blood sugar testing, foot care and smoking — a high score indicating good self-care; 4) quality of life assessed by the wound QOL short form (QOL) (Blome et al, 2014),

**Table 6. Change over time in summary of diabetes self-care activities of two groups of patients with diabetic foot ulcer.**

Distress	Intervention (n=34)	Control group (n=26)	P
BL-F1	1.0 (-15-17) (n=24)	1.0 (-6-29) (n=23)	0.701 <sup>b</sup>
F1-F2	-0.3 (-11-5) (n=20)	0.0 (-12-8) (n=16)	0.924 <sup>b</sup>
F2-F3	-1.3 (-6.5-13) (n=16)	-0.5 (-5-2) (n=13)	0.843 <sup>b</sup>
BL-F3	1.7 (±5.5) (n=16)	1.5 (±5.5) (n=13)	0.940 <sup>a</sup>

<sup>a</sup> t independent test <sup>b</sup> Mann Whitney test

Figure 2. Protocol for each visit.



consisting of 17 item with a score range of 17–85 — a high score indicated good quality of life. The secondary outcome was wound closure or changes in DFU status, assessed by the diabetic foot ulcer assessment scale (DFUAS) (Arisandi et al, 2016), consisting of 11 items with a score range of 0–98; subscales of this tool are depth of wound, wound size, size score, inflammation/infection, proportion of granulation tissue, type of necrotic tissue, proportion of necrotic tissue, proportion of slough, maceration, type of wound age, and tunneling; low scores indicating a healed wound and high scores indicating a severe wound. Data were collected three times every 2 weeks during the study period. The procedures used were carried out in accordance with the protocol shown in [Figure 2](#).

### Setting

The study was conducted at the Kitamura clinic, a private wound care clinic in a rural area of West Borneo, Indonesia. This location was chosen because approximately 40 DFU patients visit the clinic per day, and the clinic serves a multi-ethnic population.

### Statistical analyses

The consolidated standards of reporting trial (CONSORT) guidelines for randomised studies were followed (Schulz et al, 2010), and intention

to treat analyses were conducted with the SPSS 22 software (IBM Corporation). The independent-samples t-test, Mann–Whitney test, Chi-square, Fisher’s exact test, and continuity correction were used to test for possible group differences in baseline data according to demographic, social and wound characteristics. Furthermore, analysis was performed for every stage of follow-up. The authors used a t-test and Mann–Whitney test for the primary and secondary endpoints. Moreover, Kaplan–Meier analysis was performed to compare the time of healing between the intervention and control groups until the sixth week (Goel et al, 2010). To interpret any changes over time for each group, a series of analyses examined possible differences between baseline and follow-up 1 (BL–F1), follow-up 1 and follow-up 2 (F1–F2), follow-up 2 and follow-up 3 (F2–F3), and baseline and follow-up 3 (BL–F3).

## Results

### Flow chart diagram

Eligible participants were recruited from April to October 2016. A total of 91 participants were assessed for eligibility; the 60 participants that met the requirements were divided randomly into two groups. Before randomisation, 31 participants were excluded; six persons declined to participate, while 25 were excluded for other reasons. There were 34 participants allocated to the intervention group and 26 participants to the control group. During the study period, in the intervention group, there were 14 participants who dropped out; 10 participants were lost at follow up one, two participants at follow up two, and two participants at follow up three. In the control group, five participants dropped out; three participants were lost at follow up one and two participants at follow up two. In this study, seven wounds healed in the intervention group and nine in the control group [[Figure 3](#)].

### Participants’ characteristics

No difference was found between the two groups at baseline in terms of demographic characteristics, except in terms of DM duration (3.0 vs. 8.0,  $P=0.014$ ). Psychological aspects characteristics of the participants at baseline are illustrated in [Table 3](#). No significant difference was found between the two groups at baseline except in the distress characteristic (40.1 vs. 37.4,  $P=0.028$ ). No significant differences were found in wound characteristics between groups (baseline).

### Primary outcomes

#### Change in self-efficacy

The independent t-test showed changes over



**Table 7. Change over time in quality of life of two groups of patients with diabetic foot ulcer.**

Quality of life (QOL)	Intervention (n=34)	Control group (n=26)	P
QOL BL-F1	-5.4 (±9.3) (n=24)	3.9 (±6.7) (n=23)	0.553 <sup>a</sup>
QOL F1-F2	-2.1 (±9.6) (n=20)	-3.3 (±7.6) (n=16)	0.669 <sup>a</sup>
QOL F2-F3	-2.5 (±6.6) (n=16)	-5.0 (±9.0) (n=13)	0.396 <sup>a</sup>
QOL BL-F3	-7.2 (±10.2) (n=16)	-12.2 (±10.5) (n=13)	0.210 <sup>a</sup>

<sup>a</sup> t independent test <sup>b</sup> Mann Whitney test

**Table 8. Change over time in wound heal of two groups of patients with diabetic foot ulcer.**

Diabetic foot ulcer assessment (DFUAS)	Intervention (n=34)	Control group (n=26)	P
DFUAS BL-F1	4.5 (-10 - 10) (n=24)	5.0 (-12-18) (n=23)	0.364 <sup>b</sup>
DFUAS F1-F2	2.4 (±3.9) (n=20)	4.3 (±5.0) (n=16)	0.568 <sup>a</sup>
DFUAS F2-F3	3.4 (±4.6) (n=16)	2.7 (±2.2) (n=13)	0.569 <sup>a</sup>
DFUAS BL-F3	9.6 (±9.8) (n=16)	10.7 (±8.6) (n=13)	0.761 <sup>a</sup>

<sup>a</sup> t independent test <sup>b</sup> Mann Whitney test

**Table 9. Time intervention each follow up (minutes).**

	Base line (n=34)	Follow-up 1 (n=26)	Follow-up 2 (n=17)
Intervention group	25.4 (±21.9)	14.5 (±9.8)	16.1 (±13.5)

Average time of intervention = 20.02

time in the SE of participants in the two DFU groups, as illustrated in [Table 4](#). Both groups' score changes were analysed for each follow-up visit. The values for each follow up were SE BL-F1,  $P=0.444$ ; SE F1-F2,  $P=0.080$ ; SE F2-F3,  $P=0.418$ ; and SE BL-F3,  $P=0.987$ . A mean comparison showed no significant difference between the intervention and control groups.

#### Change in distress

The independent t-test showed changes in the distress experienced by participants over time in the two DFU groups [[Table 5](#)]. Both groups' score changes were analysed for each follow-up visit. The values for each follow up were DISTRESS BL-F1,  $P=0.855$ ; DISTRESS F2-F3,  $P=0.464$ ; and DISTRESS BL-F3,  $P=0.252$ . A mean comparison showed no significant difference between the intervention and control groups. However, a significant difference was found between the intervention and control groups in DISTRESS F1-F2 (0.5 vs. -1.5,  $P=0.029$ ).

#### Change in summary of diabetes self-care activities

The SDSCA change was confirmed using the Mann-Whitney test. [Table 6](#) showed there were no significant differences between groups, with the

following results: SDSCA BL-F1,  $P=0.701$ ; SDSCA F1-F2,  $P=0.924$ ; SDSCA F2-F3,  $P=0.843$ ; and SDSCA BL-F3,  $P=0.940$ .

#### Change in quality of life

The results of the independent t-test showed changes in the QOL of participants over time in the two DFU groups [[Table 7](#)]. Both groups' score changes were analysed for each follow-up visit, and the results were as follows: QOL BL-F1,  $P=0.553$ ; QOL F1-F2,  $P=0.669$ ; QOL F2-F3,  $P=0.396$ ; and QOL BL-F3,  $P=0.210$ . Thus, the mean comparisons showed no significant difference between the intervention and control groups.

#### Secondary outcomes

Kaplan-Meier analysis was performed to compare the time of healing between the intervention and control groups until the sixth week. The log rank was not found to be significant ( $P=0.218$ ); the Kaplan-Mayer curve indicated that wounds healed slightly faster in the intervention group than in the control group [[Figure 4](#)]. The changes in wound closure over time in DFU participants are illustrated in [Table 8](#). The reduction in DFU score was analysed for every follow up. The values were as follows: DFUAS BL-F1,  $P=0.364$ ; DFUAS F1-F2,  $P=0.568$ ; DFUAS F2-F3,  $P=0.569$ ; and DFUAS BL-F3,  $P=0.761$ . A mean and median comparison showed no significant difference between the intervention and control groups.

#### Discussion

This study evaluates an intervention focused on wellbeing. The results suggest that intervention cannot promote patients' wellbeing, underlined by no significant difference being found between the intervention and control groups. Statistical analysis was used to investigate any differences between the intervention and control group at each stage of follow-up. The results illustrated there was no significant difference between the intervention and control groups except in changes in distress at the second follow up (DISTRESS F1-F2, 0.5 vs. -1.5,  $P=0.029$ ). A positive mean score difference between follow-up visits meant that distress increased for the participants, while negative differences signified a decrease in patient distress. After treatment, the intervention group showed increased distress, while the control group exhibited decreased distress. Based on the baseline psychological characteristics [[Table 3](#)], the intervention group had a higher average score of distress compared to the control group, with a statistically significant difference between groups ( $P=0.028$ ). Thus, the level of distress was more dominant in the control group compared to

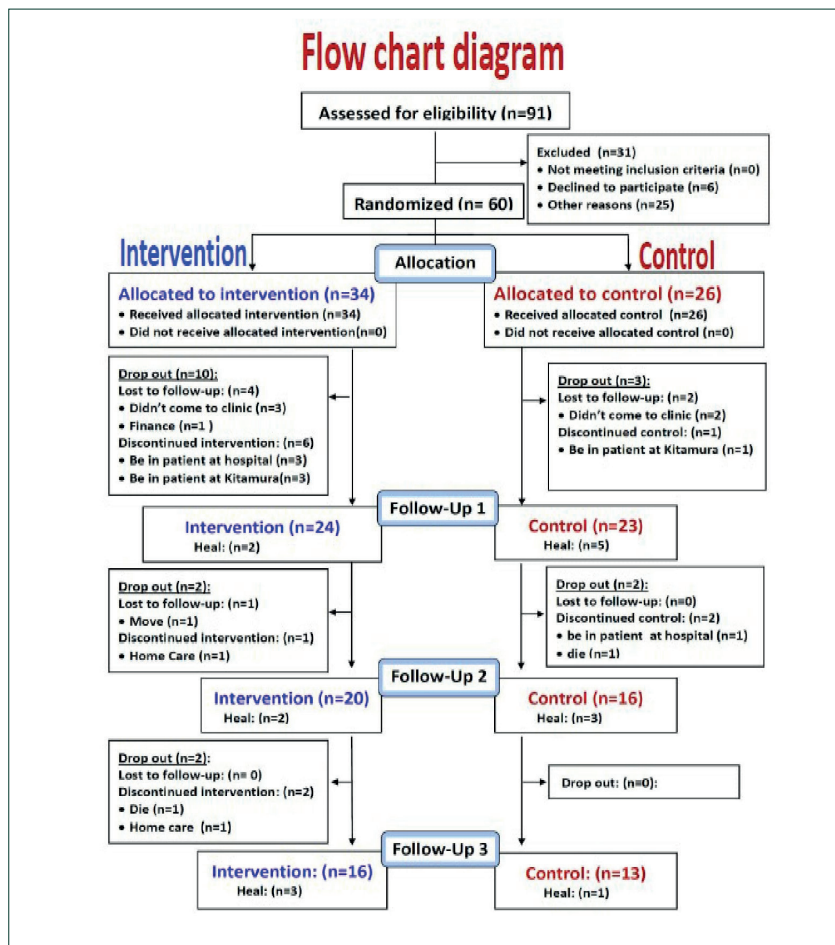


Figure 3. Flow chart showing the progress through the phases of parallel randomised trial of two groups.

the intervention group. Based on this result, the authors' hypothesis was rejected.

Two previous studies on acute wounds reported contradictory results (Holden-Lund, 1988; Emery et al, 2005); a guided imagery study suggested that the intervention reduced distress, while in an exercise study, it did not reduce distress. The different results from these studies may be associated with the different methods applied. The first study emphasised participants' ability to perform guide imagery, whereas the second placed more emphasis on physical activity.

Thus, different treatment methods related to understanding wellbeing may effectively reduce psychological issues. A similar negative study is also found in McBride's paper, where a study trial using the Decision Navigation approach to intervene patients in order to have the motivation to make decisions in relation to the series of treatment measures required in therapeutic regimens was used. Although participants rated Decision Navigation as very helpful for the intervention group, the result of statistical analyses revealed no differences in decision self-efficacy or adherence between those receiving Decision Navigation and those receiving usual care. The results of this

pilot study suggest that an intervention aimed at facilitating shared decision-making is not likely to impact patient foot behaviours at this progressed stage in the disease trajectory (McBride et al, 2016).

Another reference showed foot care knowledge (socioeconomical data) did not show a significant relationship to the occurrence of diabetic foot infection (Peters et al, 2005). So foot care knowledge is not a factor that contributes to infection in this reference. As this study does not assess foot care knowledge, it may be necessary to review for future research in order to see the link between study outcomes and foot care knowledge.

The ineffectiveness of the treatment related to understanding wellbeing in this study may have been caused by several reasons. The first was that average the intervention time for each patient was 20.02 minutes [Table 9]. The short discussion time and low frequency of only three follow-up visits for each patient was not sufficient for a discussion of patients' wellbeing. The second was the older age of the participants ( $57.2 \pm 10.0$  years). In general, older people have decreased cognitive function, which can lead to a limited ability to understand and implement a therapy regimen that is programmed or recommended by a healthcare professional. The third was the small sample. Based on previous calculations, the minimum total sample size in this study should have been 100 participants.

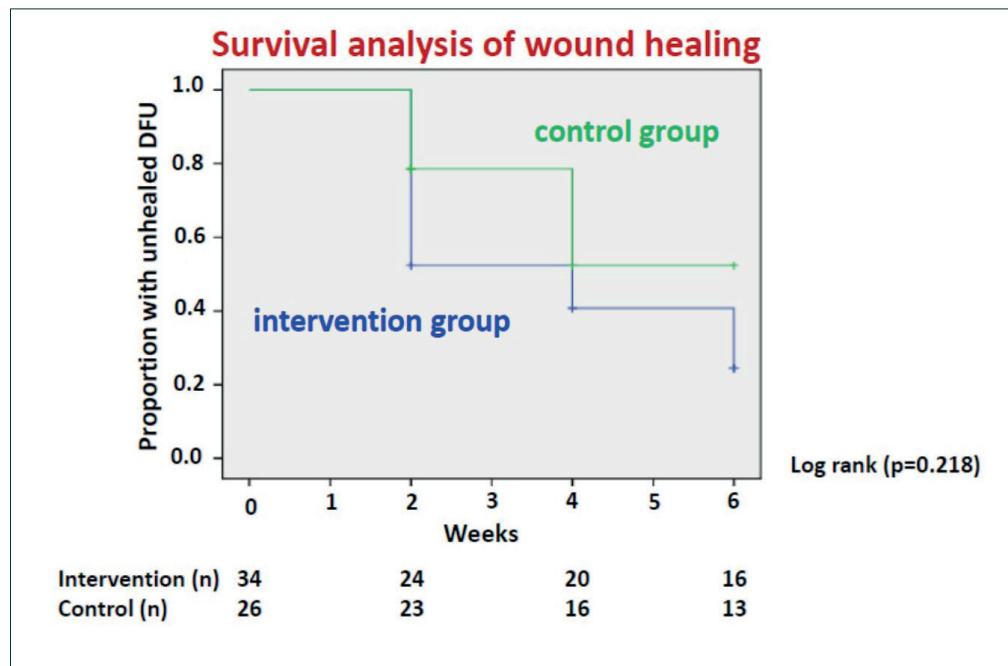
## Conclusion

In contrast to our expectations, both participants with DFU who received treatment related to their understanding of wellbeing and controls exhibited similar changes in terms of psychological aspects and acceleration of wound healing. The one exception to this was the psychological aspects of distress, which was significantly different between the two groups at the second follow up.

## Study limitations

This study has several limitations. For instance, it only focused on DFU participants and was conducted at one site. In a previous study in eastern Indonesia on the prevalence and risk factors of DFU (Yusuf et al, 2016), the participants had similar age and gender characteristics to those of the participants in the present study. However, education is higher in this region than in western Indonesia. Therefore, interventions on the understanding wellbeing may produce different outcomes in eastern Indonesia. For future research, it would be better to consider several things, such as multi-site study, the size of the sample in accordance with the calculation and the length of the study time. Finally, based

Figure 4. Proportion of unhealed diabetic foot ulcers.



on some characteristics of the study, it cannot be generalised.

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