# Mindfulness and wound healing.

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To establish a causal link between psychosocial resilience factors and wound healing and to elucidate potential underlying pathways.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON37957

**Source**
ToetsingOnline

**Brief title**
Mindfulness and wound healing

### Condition

- Other condition

**Synonym**
n.a.: Study will be carried out with healthy participants.

**Health condition**

n.v.t.: Onderzoek vindt plaats met gezonde mentaal capabele en wilsbekwame participanten.

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universiteit Maastricht
**Source(s) of monetary or material Support:** NWO

## Intervention

**Keyword:** cytokines, mindfulness, resilience, wound healing

## Outcome measures

### Primary outcome

Primary outcomes:

Wound surface is determined by digital imaging of the wound 3 - 8 days post wound-induction;

Reepithalisation is measured by comparing trans-epidermal water loss above the wound with taht above non damaged skin at 3-8 days .

### Secondary outcome

Secondary outcomes/mediators:

Cytokines IL-1α, IL-1β IL6, IL8, TNF-β) from wound exudate 3, 6, and 22 hours post wound-induction;

Daily cortisol levels (AUC) and cortisol awakening response;

Optimism and positive affect.

# Study description

### Background summary

The process of wound healing has been demonstrated to be related to psychosocial factors. Most of these studies focused on vulnerability factors impairing the wound healing process whereas psychological resilience factors (e.g. optimism, positive affect) have hardly been studied. Two studies provide preliminary evidence for the role of psychological resilience in wound healing. However, these were correlational studies and potential underlying mechanisms were not examined.
The present study attempts to establish a causal link between psychosocial resilience factors and wound healing by using an intervention to increase resilience. For this purpose mindfulness training is used because this

intervention has previously been shown to be able to increases psychological resources like positive emotions and optimism. Moreover, mindfulness is able to affect immune functioning and cortisol responsivity, the proposed key mediators of the association between psychological resources and wound healing
We hypothesize
(1) that a mindfulness intervention compared to a waiting list control condition is related to increased psychological resilience and thereby to faster wound healing (i.e. wound surface area and trans-epidermal water loss);
(2) that decreased cortisol levels and increased production of pro-inflammatory cytokines in wound fluid mediate the effects of of mindfulness/resilience on woundhealing.

## Study objective

To establish a causal link between psychosocial resilience factors and wound healing and to elucidate potential underlying pathways.

## Study design

Experimental between subjects design (single blind, randomized) with 2 conditions (waiting list control vs. mindfulness).

## Intervention

Psychological intervention: The experimental group receives a standardized 8 week mindfulness intervention adopting the mindfulness based cognitive therapy (MBCT) protocol. The control group enters a waiting list.

Wound induction: Eight small 8mm diameter wounds are created on the forearm by a safe and standardized blister-suction procedure performed by a medically trained assistant. 350 mmHg suction is applied through the holes of a template during 1 to 1 * hour creating 8 small blisters. After removal of the epidermis another sterile template with 8 wells containing a standardized isotone 0,9% NaCl in albumin solution covers the wounds to allow for exudate extraction. The well template is detached the next day, and the wound site is covered sterile.

## Study burden and risks

The risks of the blister-suction protocol are very minor. Although no skin deformation or scarring has been reported minor skin discoloration may occur in dark-skinned people. Since wounds are created in the epidermis there*s a potential risk of infection. This risk is kept at an minimum by using sterilized materials and covering the wound sites.

# Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

- Age between 18 and 40 years old
- Only participants who voluntarily signed up to follow a mindfulness training

## Exclusion criteria

- Self-reported health problems use that could influence cortisol levels, immune functioning and/or wound healing (e.g. auto-immune diseases, cancer, recent surgery, strokes, diabetes mellitus, peripheral vascular disease)
-Self-reported medication use that could influence cortisol levels, immune functioning and/or wound healing (e.g. anti-diuretics, blood pressure regulators, psychotropic medication, anti-inflammatory drugs)

- Other factors that may impact on cortisol levels, immune functioning and/or wound healing: self reported recreational drug use, heavy alcohol use (i.e. more than 10 alcoholic beverages per week for women and more than 20 for men), more than 10 units of caffeinated drinks per day
- Psychopathological conditions / psychological treatment currently or over the past 6 months / previous psychiatric hospitalization (all self report)
- Structural meditation practice (including yoga, tai chi, etc.)
- Allergic responses to adhesives, bandages, or tapes, needle or blood phobias

# Study design

## Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |

**Primary purpose:** Treatment

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 07-11-2012 |
| Enrollment: | 66 |
| Type: | Actual |

# Ethics review

Approved WMO

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| Date: | 29-10-2012 |
| Application type: | First submission |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| Other | Nederlands Trial Register nummer 13414 |
| CCMO | NL37182.068.12 |