Die Nationale Demenzstrategie

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AgeWell.de

Die AgeWell.de-Studie

Ein Demenzpräventionstrial unter COVID19- Pandemiebedingungen

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PD Dr. Melanie Luppa, Dr. Susanne Röhr
&
die AgeWell.de-Studienzentrenleiter

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Vom Risikofaktor zum Präventionsprogramm

Wissen zu Risikofaktoren

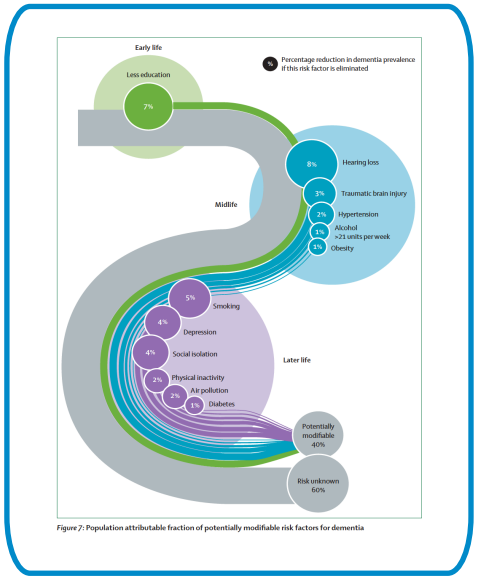
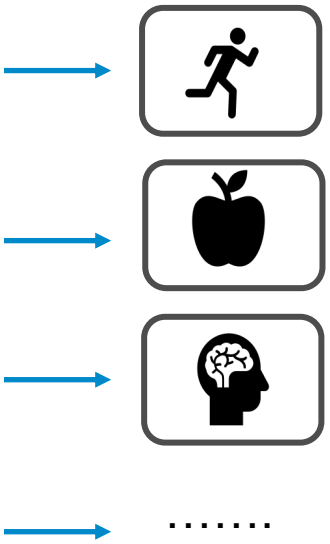


Figure 7: Population attributable fraction of potentially modifiable risk factors for dementia

Einzelne Interventions-studien



Multi-Komponenten-Interventionen

Multi-komponenten-Interventionen RCTs

Vorreiter: FINGER-Studie Finnish Geriatric Intervention Study to Prevent Cognitive Impairment and Disability
(Ngandu et al., 2015)

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AgeWell-Studie – eine Multikomponentenintervention (c-RCT) für Risikopersonen

Wer?

60-77jährige
Allgemeinarztpatienten
Risikogruppe (CAIDE-Score)

Was?

- Ernährungsberatung
- Erhöhung körperlicher Aktivität
- Kognitives Training
- Förderung sozialer Aktivität
- Intervention bei Trauer & depressiver Symptomatik
- Optimierung der Medikation

Stand?

rekrutiert n=1174
5/2018
Baseline **n=1030**
8/2018-11/2019

Follow-up
09/2020-11/2021
Ergebnisse
2022

Zülke A, Luck T, Pabst A, Hoffmann W, Thyrian JR, Gensichen J, Kaduszkiewicz H, König HH, Haefeli WE, Czock D, Wiese B, Frese T, Röhr S, Riedel-Heller SG. AgeWell.de - study protocol of a pragmatic multi-center cluster-randomized controlled prevention trial against cognitive decline in older primary care patients. BMC Geriatr. 2019 Aug 1;19(1):203. doi: 10.1186/s12877-019-1212-1.

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Die deutsche AgeWell-Studie: Aktueller Stand

StudienteilnehmerInnen (n = 1030)	
Alter, M (SD)	69.0 (4.9)
Geschlecht, weiblich %	52.1%
Bildung, niedrig, mittel, hoch, %	24.4, 53.0, 22.6
Kog. Leistung (MoCA), M	24.5
Kog. Leistung (MoCA), ≥ 26, %	39.4%
Demenzrisiko (CAIDE), M (SD)	10.2
Interventionsgruppe, %	47.3%

International Journal of *Environmental Research and Public Health*

MDPI

Article

Recruitment and Baseline Characteristics of Participants in the AgeWell.de Study—A Pragmatic Cluster-Randomized Controlled Lifestyle Trial against Cognitive Decline

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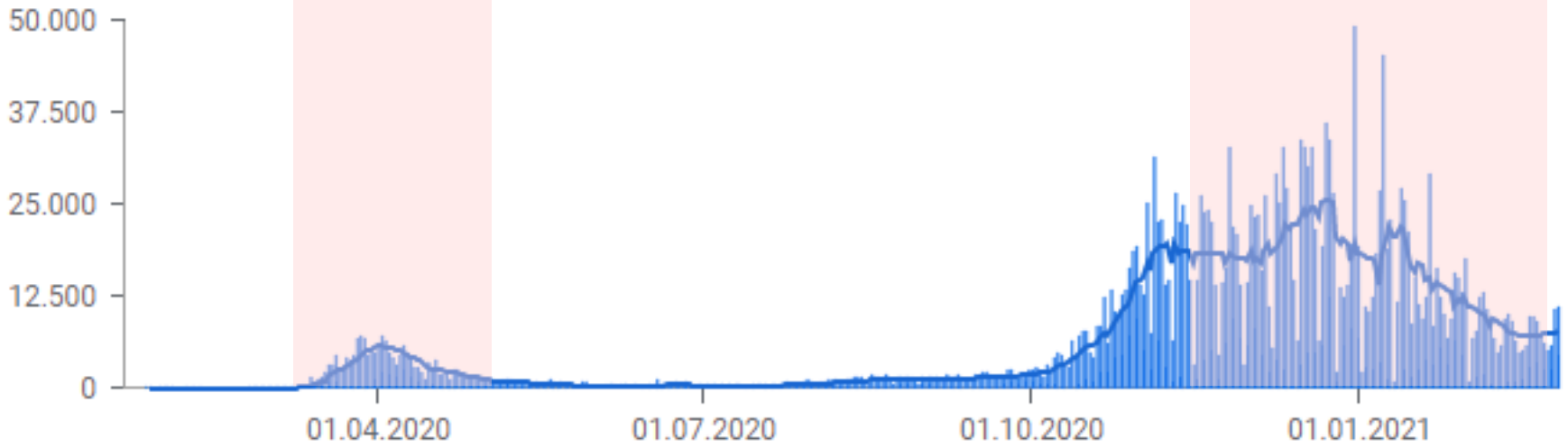
Die deutsche AgeWell-Studie: Timeline

Lockdown

Baseline:
08/2018-11/2019 - Interventionsperiode - Nachbefragung:
08/2020-11/2021



COVID-19-Pandemie: Impact auf AgeWell-Studie

1. Infektionsschutzmaßnahmen - insbesondere der Lockdown schränken **interventionsrelevante Lebensstilbereiche** ein (v.a. körperliche und soziale Aktivität, psychisches Wohlbefinden)

2. Hohes **Infektionsgeschehen lässt keine persönlichen Interviews im Rahmen der 2-Jahre-Nachbefragung zu** (Endpunkt des Trials) – Assessments müssen pausieren – Verlängerung zwingend

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COVID-19-Pandemie: Aktuelles Vorgehen und Maßnahmen in AgeWell.de

1. Zusätzliches **postalisches Survey** mit allen Studienteilnehmern im 1. und 2. Lockdown:
   - Veränderungen und wahrgenommene Einschränkungen im Alltag
   - Einstellungen zu COVID-19 und Infektionsschutzmaßnahmen
   - Soziale und psychische Gesundheitsoutcomes, Resilienz
   - Interventionsgruppe: wahrgenommene Einschränkungen in Lebensstilbereichen, Motivation
2. **Hygiene- und Schutzprotokoll** zur persönlichen Testung bei zulässigem Infektionsgeschehen und Testräume in Studienzentren
3. **Telefonische Kontakte** zur Stärkung der Adhärenz (booster-Sessions) bei Interviewpausierungen

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AgeWell-Studie – Teil einer weltweiten Community

STUDY PROTOCOL Open Access

AgeWell.de – study protocol of a pragmatic multi-center cluster-randomized controlled prevention trial against cognitive decline in older primary care patients

Check for updates

Andrea Zülke[1*†], Tobias Luck[1,2†], Alexander Pabst[1], Wolfgang Hoffmann[3,4], Jochen René Thyrian[4], Jochen Gensichen[5], Hanna Kaduszkiewicz[6], Hans-Helmut König[7], Walter E. Haefeli[8], David Czock[8], Birgitt Wiese[9], Thomas Frese[10], Susanne Röhr[1†] and Steffi G. Riedel-Heller[1†]

Abstract

Background: In the absence of treatment options, the WHO emphasizes the identification of eff strategies as a key element to counteract the dementia epidemic. Regarding the complex nature simultaneously targeting multiple risk factors should be particularly effective for prevention. So fa few such multi-component trials have been launched, but yielding promising results. In Germany initiatives are lacking, and translation of these complex interventions into routine care was not y *AgeWell.de* will be conducted as the first multi-component prevention trial in Germany which is the primary care setting.

Methods: *AgeWell.de* will be designed as a multi-centric, cluster-randomized controlled multi-compo trial. Participants will be older community-dwelling general practitioner (GP) patients (60–77 years; *n* = increased dementia risk according to CAIDE (Cardiovascular Risk Factors, Aging, and Incidence of Dem Risk Score. Recruitment will take place at 5 study sites across Germany. GP practices will be randomize intervention A (advanced) or B (basic). GPs will be blinded to their respective group assignment, as wi conducting the randomization. The multi-component intervention (A) includes nutritional counseling, cognitive training, optimization of medication, management of vascular risk factors, social activity, and specific interventions targeting grief and depression. Intervention B includes general health advice on components and GP treatment as usual. We hypothesize that over the 2-year follow-up period the in will benefit significantly from the intervention program in terms of preserved cognitive function/delay (primary outcome), and other relevant (secondary) outcomes (e.g. quality of life, social activities, depre symptomatology, cost-effectiveness).

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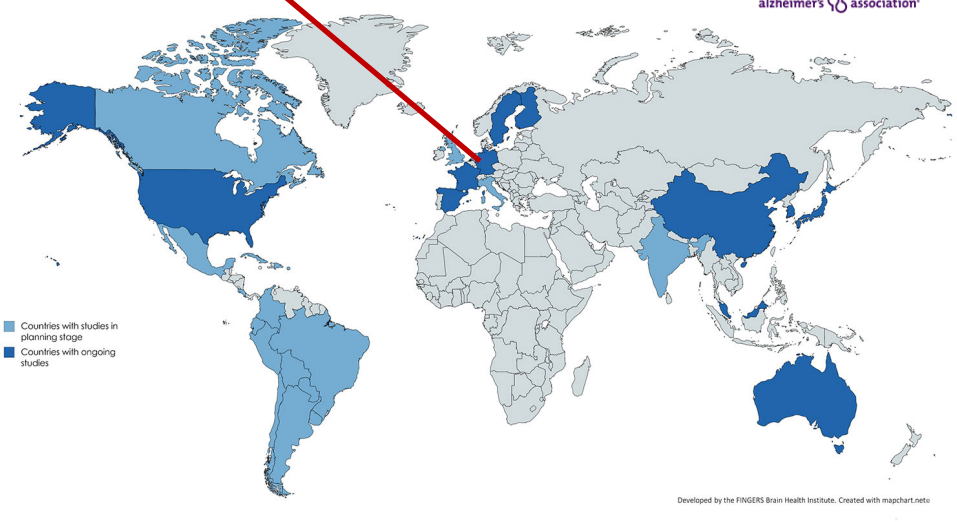
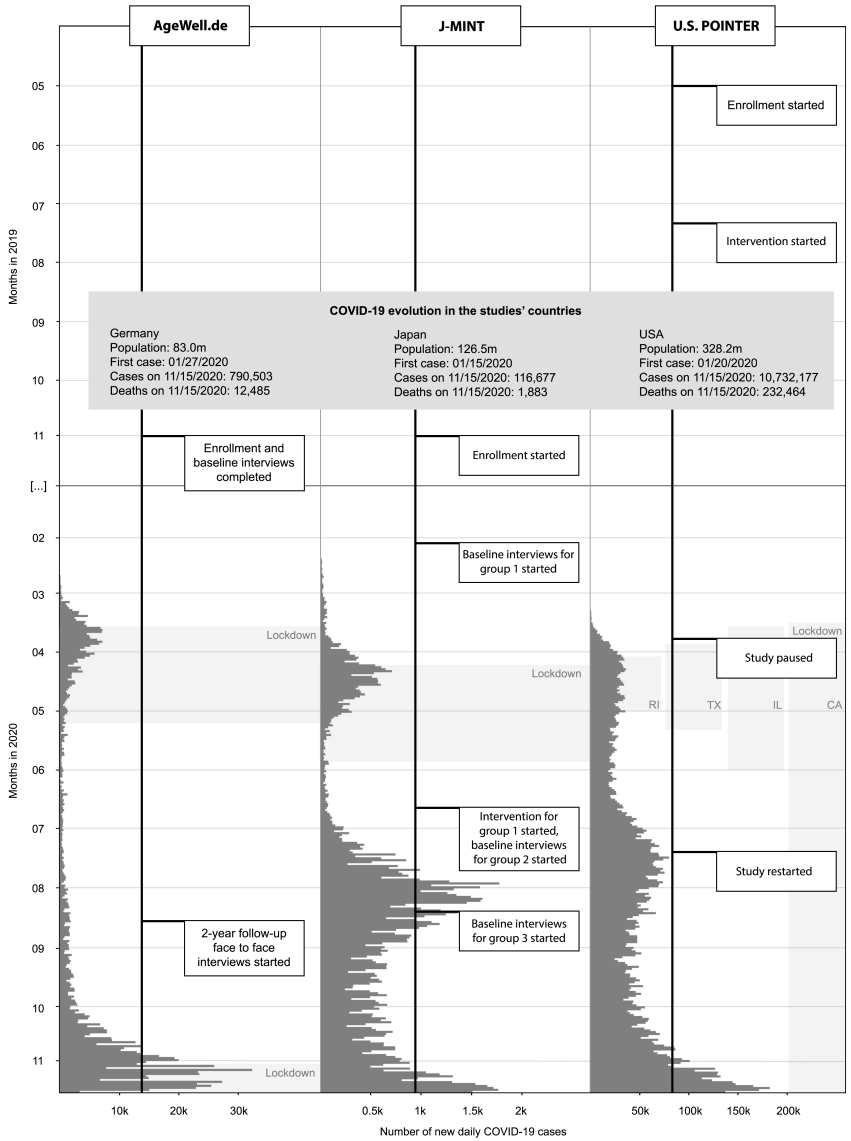
WORLD WIDE FINGERS
alzheimer's association



Impact der COVID-19-Pandemie international



Kollaborative WW-FINGERS-Publikation zum Impact der COVID-19-Pandemie auf das statistische Design und Analysepläne für Mulitkomponenten-Interventionstudien

- Erfahrungen und Erkenntnisse federführend von AgeWell.de (D), mit J-MINT (Japan) und U.S.Pointer (USA)
- Einblicke und Ableitungen von Empfehlungen für vergleichbare Studien und geplante Studien

Publikation am 11.03.21

Röhr et al. in Alzheimer's & Dementia: Translational Research & Clinical Interventions (TRCI)

Implikationen / Schlussfolgerungen

- Umfangreiche Maßnahmen zur **Anpassung** der Studie an Pandemielage
- **Zusätzliche Datenerhebung** zur Einordnung des Pandemie-Impacts und Abgleich mit der Allgemeinbevölkerung (siehe Exkurs)
- **Kontinuierlicher internationaler Austausch** mit internationaler Wissenschafts-Community zur Entwicklung von Adaptionsstrategien
- **Unausweichliche Verzögerungen** in den geplanten Nachbefragungen durch Dynamik des Infektionsgeschehens; zieht Projektverlängerung nach sich….

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Exkurs I: Abgleich der Survey-Daten aus AgeWell.de mit repräsentativer Studie in der Altenbevölkerung

Work in Progress:

Abgleich der Survey-Daten aus AgeWell.de mit repräsentativer Studie in der Altenbevölkerung (n = 1005, Alter > 65 Jahre) mit identischen Messinstrumenten

RESEARCH ARTICLE Open Access

Mental wellbeing in the German old age population largely unaltered during COVID-19 lockdown: results of a representative survey

Susanne Röhr[1,2*], Ulrich Reininghaus[3,4,5] and Steffi G. Riedel-Heller[1]

Abstract

Background: Older individuals are at increased risk of a severe and lethal course of COVID-19. They have typically been advised to practice particularly restrictive social distancing ('cocooning'), which has sparked much debate on the consequences for their mental wellbeing. We aimed to provide evidence by conducting a representative survey among the German old population during COVID-19 lockdown.

Methods: A computer-assisted standardized telephone interview was conducted in a randomly selected and representative sample of the German old age population ($n = 1005$; age ≥ 65 years) during the first lockdown in April 2020. Assessments included sociodemographic factors, aspects of the personal life situation during lockdown, attitudes towards COVID-19, and standardized screening measures on depression, anxiety, somatization, overall psychological distress (Brief Symptom Inventory/BSI-18) and loneliness (UCLA 3-item loneliness scale). Sampling-weighted descriptive statistics and multiple multivariable regression analyses were conducted.

Results: Participants were $M = 75.5$ ($SD = 7.1$) years old; 56.3% were women. At data collection, COVID-19 lockdown had been in force for $M = 28.0$ ($SD = 4.8$) days. Overall, older individuals were worried about COVID-19, but supportive of the lockdown. Mean BSI-18 scores were 1.4 for depression, 1.6 for anxiety and 2.2 for somatization as well as 5.1 for global psychological distress. These figures did not indicate worse mental wellbeing, given normative values established by studies before the pandemic (2.0, 1.6, 2.4, 6.0, respectively). The prevalence of loneliness was 13.1%, which also fell within a range of estimates reported by studies before the pandemic. There were only few significant associations of aspects of the personal life situation during lockdown and attitudes towards COVID-19 with mental wellbeing. Resilience explained a large amount of variance.

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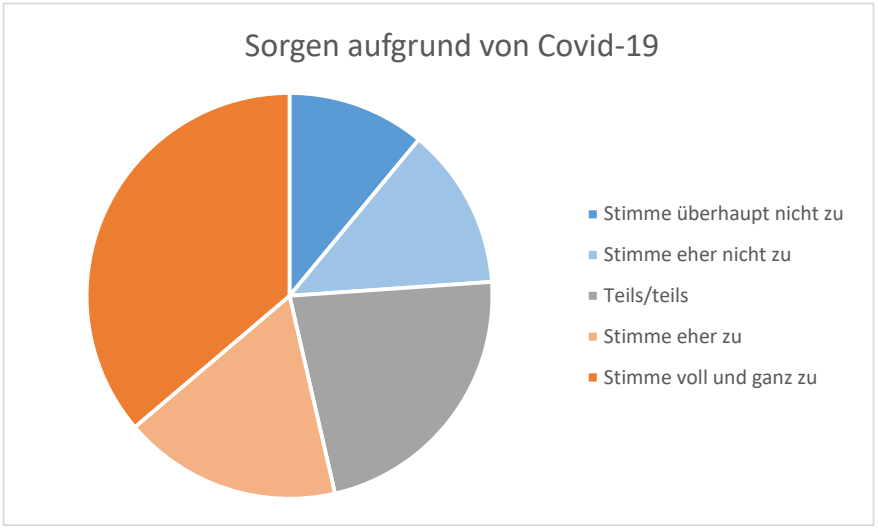
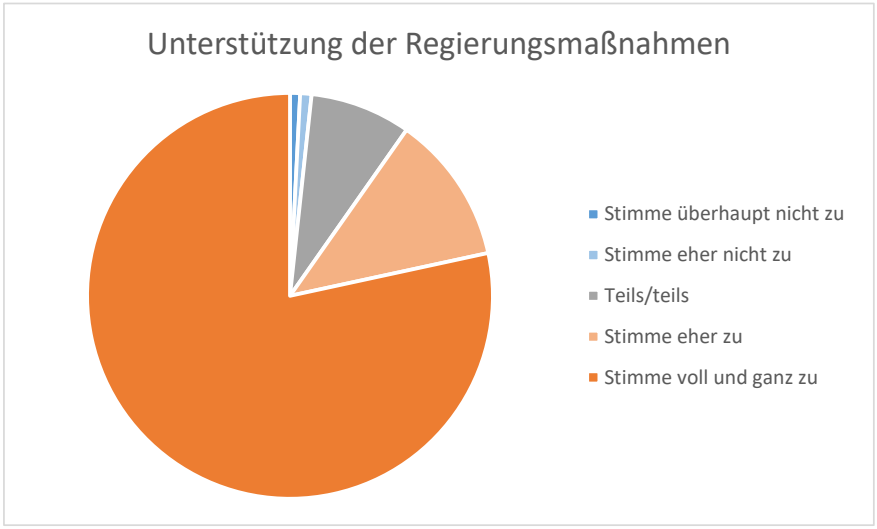
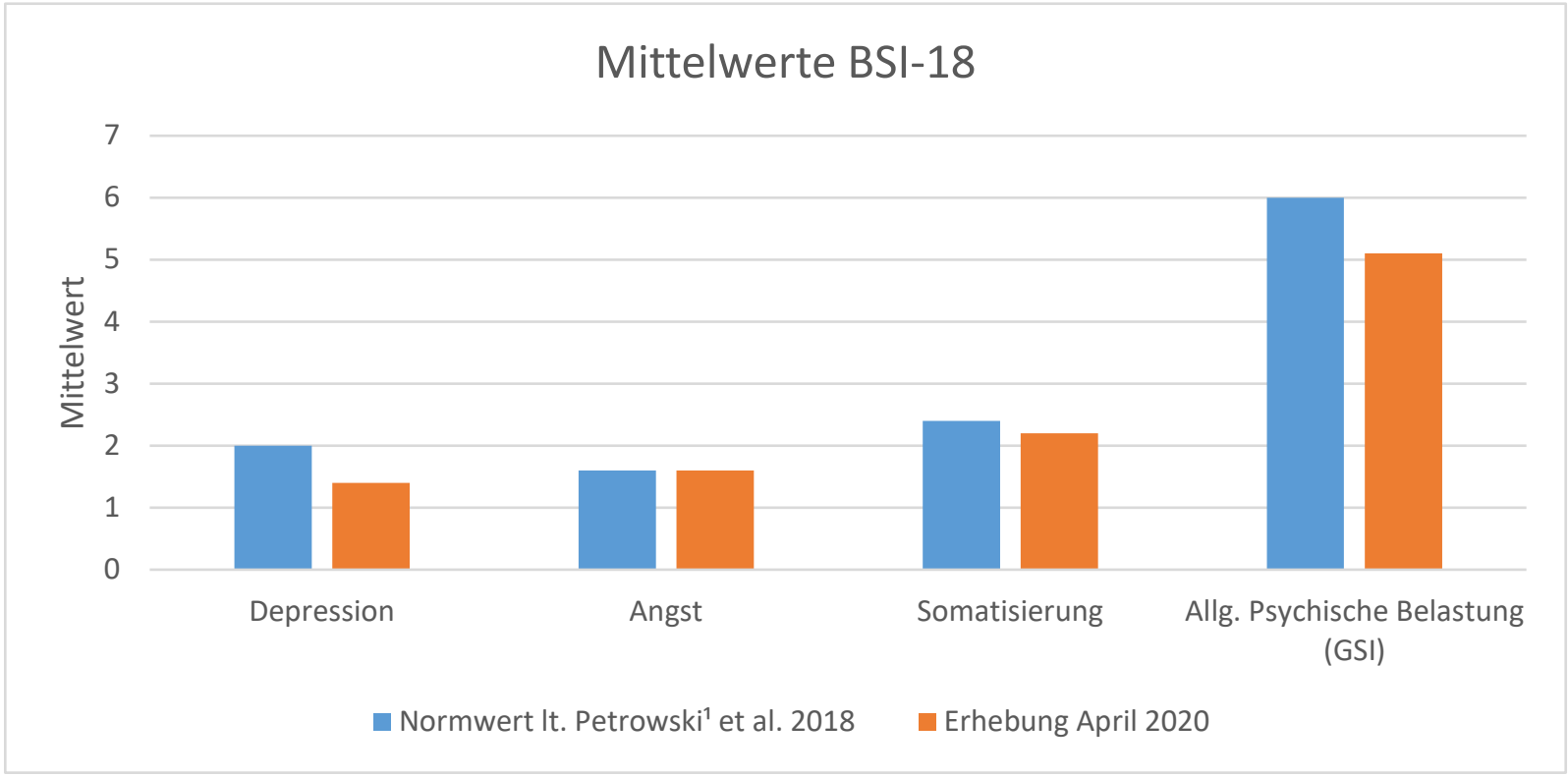
Exkurs II: Repräsentativerhebung im 1. Lockdown: Einstellungen

- Teilnehmer: n= 1005, mittleres Alter *M*=75.5 (*SD*=7.1) Jahre, 56.3% Frauen
- COVID-19-Lockdown war in Kraft für *M*=28.0 (*SD*=4.8) Tage
- Ältere Menschen waren besorgt über COVID-19, befürworteten jedoch Lockdown





Exkurs III: Repräsentativerhebung im 1. Lockdown: Psychische Gesundheit



[1] Petrowski K, Schmalbach B, Jagla M, Franke GH, Brähler E. Norm values and psychometric properties of the brief symptom inventory-18 regarding individuals between the ages of 60 and 95. BMC Med Res Methodol. 2018;18(1):164.

[2] Röhr, S., Reininghaus, U., & Riedel-Heller, S. (2020, July 15). Mental and social health in the German old age population largely unaltered during COVID-19 lockdown: results of a representative survey.PrePrint: https://doi.org/10.31234/osf.io/7n2bm

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& die AgeWell.de-Studienzentrenleiter